HOUSE OF COMMONS SESSION 1998–99

SCIENCE AND TECHNOLOGY COMMITTEE

First Report

SCIENTIFIC ADVISORY SYSTEM: GENETICALLY MODIFIED FOODS

Volume II

Appendices to the Minutes of Evidence

Ordered by The House of Commons *to be printed*
12th May 1999

LONDON: THE STATIONERY OFFICE
£14·70

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286–II

The Science and Technology Committee is appointed under Standing Order No. 152 to examine the expenditure, administration and policy of the Office of Science and Technology and associated public bodies.

The Committee consists of 11 Members. It has a quorum of three. Unless the House otherwise orders, all Members nominated to the Committee continue to be Members of it for the remainder of the Parliament.

The Committee has power:

(a) to send for persons, papers and records, to sit notwithstanding any adjournment of the House, to adjourn from place to place, and to report from time to time;

(b) to appoint specialist advisers either to supply information which is not readily available or to elucidate matters of complexity within the Committee's order of reference;

(c) to communicate to any other such committee and to the European Scrutiny Committee, to the Committee of Public Accounts, to the Deregulation Committee and to the Environmental Audit Committee its evidence and any other documents relating to matters of common interest; and

(d) to meet concurrently with any other such committee for the purposes of deliberating, taking evidence, or considering draft reports or with the European Scrutiny Committee or any sub-committee thereof for the purposes of deliberating or taking evidence.

The following were nominated Members of the Committee on 14 July 1997:

Mr David Atkinson
Mr Nigel Beard
Dr Michael Clark
Mrs Claire Curtis-Thomas
Dr Ian Gibson
Dr Lynne Jones
Mr Nigel Jones
Dr Ashok Kumar
Mrs Caroline Spelman
Dr Desmond Turner
Dr Alan W. Williams

Dr Michael Clark was elected Chairman on 30 July 1997.

On 22 June 1998 Mrs Caroline Spelman was discharged from and Mrs Jacqui Lait added to the Committee.

On 30 November 1998 Mr David Atkinson was discharged from and Mr Ian Taylor added to the Committee.

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UNPRINTED MEMORANDA

Additional Memoranda have been received by the following and have been reported to the House, but to save printing costs they have not been printed and copies have been placed in the House of Commons Library where they may be inspected by Members. Other copies are in the Record Office, House of Lords, and are available to the public for inspection. Requests for inspection should be addressed to the Record Office, House of Lords, London, SW1. (Tel 071-219 3074). Hours of inspection are from 9.30 am to 5.30 pm on Mondays to Fridays.

1. Appendices to Memorandum submitted by Iceland plc
2. Appendices to Memorandum submitted by Professor Janet Bainbridge
3. Appendices to Memorandum submitted by Dr Stanley Ewen
4. Memorandum submitted by Dr Arpad Pusztai
5. Memorandum submitted by the National Farmers' Union
6. Appendices to Memorandum submitted by the Biotechnology and Biological Sciences Research Council
7. Annexes to Memorandum submitted by the Department of the Environment, Transport and the Regions
8. Appendices to Memorandum submitted by Friends of the Earth, England, Wales and Northern Ireland
9. Appendices to Memorandum submitted by the Consumers' Association
10. Appendices to Memorandum submitted by the Country Landowner's Association
11. Annexes to Memorandum submitted by the Society, Religion and Technology Project, Church of Scotland
12. Annexes to Memorandum submitted by the Ministry of Agriculture, Fisheries and Food, the Department of Health, the Scottish Office, the Welsh Office and the Northern Ireland Office
13. Appendix to Memorandum submitted by Dr Andrew Stirling and Mr Robin Grove-White
14. Appendices to Memorandum submitted by the Institute of Science in Society
15. Appendices to Memorandum submitted by the Institute of Biology, the Association of Applied Biologists, the British Crop Protection Council, the British Ecological Society, the British Grassland Society, the British Psychological Society, the Institute of Horticulture, the Nutrition Society and the Systematics Association
16. Appendices to Memorandum submitted by the Royal Commission on Environmental Pollution
17. Appendices to Memorandum submitted by Monsanto plc
18. Appendices to Memorandum submitted by J. Sainsbury plc
19. Appendix to Memorandum submitted by Mrs Barbara Saunders

APPENDICES TO THE MINUTES OF EVIDENCE

TAKEN BEFORE THE SCIENCE AND TECHNOLOGY COMMITTEE

APPENDIX 1

Memorandum submitted by Somerfield Stores Limited

1. Introduction

Somerfield Stores Limited merged with Kwik Save Limited last year. As a result of the merger the expanded group now operates 1,400 stores in a wide variety of locations throughout England, Scotland and Wales. The stores are of varying sizes but are very typically located in the High Street and in community centres. We sell approximately 5,000 lines under our own label and a limited number of these are labelled as being produced from genetically modified ingredients. We are obviously therefore concerned with the quality of the advice and customer reaction to such advice.

2. The Approval Process

Somerfield have supported the approvals process relating to genetically modified foods and once a product has been declared as safe we have been happy to use it in our own label products. We are neither for nor against biotechnology—our concern is to sell safe foods to customers who can enjoy that food and continue to consume it on an ongoing basis. To that end our requirement is for the approvals process to be robust and command confidence. There have been concerns raised by a number of groups as to the robustness of the regulatory approval process and these concerns need to be considered by an enquiry so as to either lay them to rest as being spurious, or to incorporate them into the approval process to ensure that greater confidence can be achieved in the decision making process.

3. Our main concern with regard to the whole area of genetically modified foods has been the separate approvals given by different expert Committees, working under different Ministries. We believe there is need to bring decision making together to ensure that the full approval process covers all the appropriate areas that need investigating and ensures that any gaps are avoided. We are aware that the Government have been looking at an over-arching committee and we would support such a proposal on the assumption that it will fill in those all important gaps. We are also aware of some criticisms of ACRE which may not consider all the implications when granting approvals and that the constituency of its members infers a bias towards the biotechnology industry.

4. Advisory Committees

The Advisory Committee structure is one that has worked well in the past but we must be aware of the potential criticisms of vested interest and this can be addressed by transparency. We have, as retailers, argued that the Committee structures need to be reviewed to ensure that the supply chain is better represented on all of the Committees. We fully appreciate that the Committees consider detailed scientific information and that experts are therefore required to digest that information and make judgment upon it. However, the food chain are involved in the consequences of the judgment and need therefore to have an input into the decision making process. This has been recognised in part, by the appointment of consumer representatives to all expert Committees. We would suggest that the same arrangement should equally be made to ensure supply chain members are represented on all Committees.

5. Expert Committees must ensure that they consider the best advice available. Currently you are expected to register your interests prior to serving on a Committee but are excluded from discussions on any area where you may have a vested interest. As a retailer of food we would find it impossible to attend many of these Committees and take part in any of the conversations because we are involved in the retailing of virtually every type of food on sale in the UK. This is an important issue and it needs to be considered. Surely the best way forward is for members to declare their interests at the time of their appointment. Once they are appointed they can remind the Committee of their interests but do need to be involved in the debate as it is exactly because they have this industrial and commercial knowledge that they are going to be of benefit to the Committee. Provided the Committee operates in a much more transparent way with full publication of proceedings then it will be possible to prove that individual members were not abusing their appointment.

6. In order to facilitate the best discussion possible on any topic more transparency is required in the whole process of consideration of issues before Scientific Committees. We would recommend the BSE Inquiry as an excellent example of the way that Committees could change in future. We believe that genetically modified foods would benefit from the Committees asking for comments prior to the consideration of an issue. If this is done publicly then all those who have an interest can comment. The Committee should consider those comments and should be expected to address all such serious concerns. If the Committee meeting minutes were available on the Internet, and the decisions were thus widely disseminated, then those who argue that the existing system fails to take account of particular considerations will be shown to be wrong. Obviously Committees would be expected to only deal with serious concerns and that would have to be defined to ensure that expert Committees were not completely overloaded. We fully believe that such changes will bring benefits and increase customer confidence. We, and I am sure many of our competitors, would feel that we were able

to be more confident in such an open process. I am sure that we would do our best to provide assistance to such expert groups.

7. Equally expert Committees may well want to consider a more flexible membership where they may wish to bring in particular experts to assist in the consideration of a particular topic. Whether it is possible to operate with a more flexible framework of membership we are not sure, but do believe it is something that could be considered.

8. UK, EU and GATT

We must recognise the United Kingdom is an integral part of the European Union and that the European Union supports GATT agreements. Within the GATT agreements there are provisions for the approval of genetically modified foods for world trade, subject to approval to the best science available. This needs to be well defined in order to be able to ensure that there is an even understanding between the UK, the EU, and other countries involved in this technology—particularly America. If this is well defined then many of the arguments we are currently enjoying may be avoided.

9. Flexibility

We need to consider whether it is easily achieved, having defined what we mean by safety and good science. At the present time each individual crop has to come forward for approval. As the technology develops more approvals will be required which will be an even more onerous task for the expert Committees. Consideration must be given to how the approval processes can cope with an increased workload. Some sort of flexibility will be required but it needs to be properly defined, and more importantly needs to be openly defined, so that consumers can buy into it.

10. Over-arching Bodies

Clearly there are many considerations with regard to genetically modified foods and crops. We have to define whether the product is safe in terms of food use, and equally we have to consider its impact in the Environment and upon wild life, the landscape, etc. Many of the criticisms at the present time related to the gaps which are perceived between different expert Committees. An over-arching Committee capable of considering the topic in the round has to be the right way forward.

11. The Government as an intelligent customer

The Government must be an intelligent customer for the information that will be provided. Certainly expert advice is required in order to assess many of the issues around this topic. To that end expert Committees almost certainly are required to give advice. One of the views though that is important is to ensure that decisions are made ethically, in an open and inclusive way, rather than narrow or academic.

12. More importantly the Government must act as an intelligent customer in converting that information into practical advice. To that end practical advice is required to spell out the requirements for such issues as crop segregation and product labelling. This will seek to ensure that academic or theoretical recommendations are put into practice, and more importantly take account of the challenges posed by putting into practice such recommendations within an extended food chain. This will allow for the better communication of information to customers and to the public at large. To that end this is a vital issue on which the Government do not have such a good track record and is something that must be considered more fully. The scientific evaluation of issues is vitally important, but turning it into practical advice is equally as important, the consequences of which we ignore at our peril.

18 February 1999

APPENDIX 2

Letter to the Chairman of the Committee from the Chairman of the House of Lords European Communities Committee Sub-Committee on Agriculture, Fisheries and Food

EC REGULATION OF GENETIC MODIFICATION IN AGRICULTURE

I understand that your Committee, as part of its enquiry into the Scientific Advisory System, is to conduct a case study into the advice given to Government on genetically modified foods. As you may know, the House of Lords European Communities Committee Sub-Committee on Agriculture, Fisheries and Food, which I chair, recently produced a report on the EC regulation of genetic modification in agriculture, and made some recommendations on the UK regulatory system. I thought that I would write to you on behalf of the Sub-Committee to give you a summary of our views.

On the safety of novel, including genetically modified, foods we considered that the examination given to all applications to market novel foods was thorough and appropriate, and we found no reason to doubt the safety of foods approved. The process of assessment by ACNFP we found to be as open as could be hoped for, with all conclusions and minutes of meetings being published. More is known today about new foods approved than about many of the staples of our diet (paras 109–116).

As far as environmental assessments are concerned, we thought that ACRE dealt expertly with individual applications to release. However we considered that what was lacking was an advisory body to examine the general issues which arise from the use of genetic modification in agriculture, and to give a continuous and detailed consideration of policy. It could have issues referred to it by Ministers or ACRE but should also be able to act on its own initiative. It should be able to commission research, and ensure that it was acted upon. For instance it could examine the regulations and monitoring of herbicide tolerant crops and the impact on agriculture in general of changes to pest control arising from the use of GM crops. Membership of the committee should be wide-ranging (including cross-membership with other committees), and include consumer representation. It should engage in consultation with interested groups. We did not address the issue of such a committee's place in the Government framework (eg to whom it should report, who should appoint the members) (paras 151–153).

So far as ACRE is concerned, we considered its expertise should be broadened, and its remit adjusted, to enable it to consider, for example, indirect and cumulative environmental effects when judging individual applications. We were also most concerned at the body of knowledge that would be lost if 10 of its 13 members were to retire as scheduled in April, and urged the Government to review this situation (paras 148–149).

Our report also covered in some detail the EC regulatory system, including Community scientific advice (paras 159–170). The European framework is crucial, and you may wish to consider it in your enquiry.

Our Sub-Committee will look forward with interest to your conclusions.

Incidentally the Government response to our Report is due by 21 March, after which there will be a debate in the House.

25 February 1999

APPENDIX 3

Memorandum by the Microbiology Advisory Committee to the Department of Health

1. Introduction

The Microbiology Advisory Committee (MAC) is formed from specialist representatives from academia, the NHS and PHLS to advise the Department of Health, through the MDA, on disinfection and sterilisation practices applicable in and appropriate to the Health Service. The MAC also advises on the preparation and ratification of Departmental guidance on microbiological aspects of equipment used and intended to be used in the Health Service.

2. Scientific Advisory System: Genetically Modified Food

The Microbiology Advisory Committee has not provided advice to the Government on issues relating to Genetically Modified Foods.

2 March 1999

APPENDIX 4

Letter to the Committee Specialist from Mr John Monks, General Secretary, Trades Union Congress

You will recall that the TUC made a written submission last year to the Committee's inquiry into the Scientific Advisory System. We understand that the Committee is now conducting a case study relating to genetically modified foods.

In particular, we are aware that this latest study is examining whether there is value in the proposal for an overarching body to advise on and oversee all genetically modified food issues.

Our earlier evidence stressed the contribution made to the scientific advisory system of the stakeholder approach adopted by the Health and Safety Commission, in particular because this approach ensures that rather than seek a sometimes unattainable objective scientific opinion, differing views are obtained from differing sources and can then be exposed to scrutiny and decision. This also therefore contributes transparency to the process, with bias welcomed and open rather than hidden and furtive.

The TUC believes that this applies to the issue of genetically modified foods, and in general to the biotechnology industry. Indeed the TUC General Council agreed earlier this month that we should press the Government to establish just such a process to oversee the biotechnology industry.

A National Biotechnology Council representing employees and employers, consumer and environmental groups, as well as professional scientists, could fulfil the twin tasks of overseeing the proliferation of advisory bodies in this field, and tackle the ethical questions which are not currently handled by any of those advisory bodies.

I hope that this contribution is useful to the Committee. We would welcome any support for such a Council which the Committee could give.

10 March 1999

APPENDIX 5

Memorandum submitted by the UK National Committee for Microbiology (UKNCM)

Introduction

The recently formed UK National Committee for Microbiology (UKNCM) is a coordinating body that represents the discipline of microbiology in professional matters.

UKNCM is comprised of representatives of all the national learned societies and associations, in both science and medicine, whose members are active in the subject area of microbiology, including virology. UKNCM provides a common voice for the 20 or so UK microbiological societies without diminishing the authority and individuality of these constituent bodies.

In line with its primary responsibility for professional affairs, UKNCM is formally constituted as a cluster of affiliated societies within the Institute of Biology.

Matters of particular concern to UKNCM are:—

(a) presenting an expert view from microbiologists to Government, Research and Funding Councils, and industry on all relevant matters of policy and implementation;

(b) establishing and maintaining appropriate educational standards in microbiology, and having these recognised through individuals' accreditation as certified microbiologists.

UKNCM holds a database of microbiological experts covering the complete subject spread of the discipline and, through its network of contacts with its own constituent societies and with the Institute of Biology, is ideally placed to ensure that authoritative opinion is readily available on all matters microbiological. Where such issues are of concern, UKNCM should be the first point of contact.

UKNCM contributed to the earlier inquiry into the Scientific Advisory System when its views were formally incorporated into the response from the Institute of Biology.

Adequacy and Quality of Scientific Advice at Present

Issues such as those arising with Genetically Modified (GM) foods are often extremely complex, and where advice is sought from particular specialist groups it is inevitable that that advice will come with the major focus determined by the interests of the group. For example, the food industry will very properly stress the positive gains to be achieved with GM foods, whereas environmental groups will express their legitimate concerns over possible negative effects on biodiversity and the spread to other species of properties that would there prove detrimental.

More balanced views, considering the issues in a more holistic manner, are likely to be obtained from the relevant independent learned societies, from chartered bodies, and from groups such as UKNCM and UK Life Sciences Committee (UKLSC) recently set up with the specific objectives of improving the quality and co-ordination of advice given to Government on particular scientific issues.

Role and Framework of Advisory Committees

The principal value of governmental advisory committees arises from their long-term involvement with a defined area of major concern. Many of the specific issues on which Government requires scientific advice do not, however, match exactly the remit and experience developed within any one particular advisory committee. Under such circumstances, advisory committees should be encouraged to make more use of co-option, and the commissioning of information and opinions from the scientific community at large through the learned societies and chartered bodies.

Ability of the Current System to Respond to Rapid Scientific Developments

There are two separable problems; one mechanistic and the other strategic.

In view of the diversity of individuals and groups that may require to be consulted, the time scale within which the scientific community is asked to respond is often totally unrealistic.

It is seldom the scientific developments which arise with such rapidity, but rather it is the appreciation within Government of their significance that determines the need for a rapid response.

Both the identity of likely future issues of national importance, and the formulation of considered opinion as to how they should be addressed, could be greatly improved through a more prolonged and active dialogue between government and the scientific community at large. Once again the ideal channels for such a communication would be through the learned societies and chartered bodies.

Value in the Proposal for an Overarching Body to Advise on and Oversee all Genetically Modified Food Issues

GM foods can most sensibly be dealt with in the context of the whole range of issues arising from the production, distribution and consumption of foods. That is to say, responsibility for GM foods should be in the remit of the Foods Standards Agency.

Capacity of Government to be an "Intelligent Customer" for the Advice it Receives

The problems which have arisen over the introduction of GM foods clearly illustrate that scientific and technical advice, and decisions based thereon, must be set in the wider context of the public's understanding and acceptance of the issues involved; with the latter not necessarily being greatly influenced by the former. Government, and scientists, must clearly recognise that it is no longer possible to be simply prescriptive, even in situations where the scientific evidence appears irrefutable.

With regard to this last point, and the issues raised earlier in respect of the role of learned societies in fostering a prolonged and active dialogue between Government and the scientific community, it is significant that the February issue of "Microbiology Today", the house magazine of the Society for General Microbiology, features three authoritative articles on separate aspects of the GM foods debate.

9 March 1999

APPENDIX 6

Memorandum submitted by Nuffield Council on Bioethics

Introduction

The Nuffield Council on Bioethics is an independent body founded in 1991 and currently supported by funds from the Nuffield Foundation, the Wellcome Trust and the Medical Research Council. Its terms of reference are:

1. To identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;

2. To make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;

3. In the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

The Council has produced Reports on: *Genetic screening: ethical issues* (1993); *Human tissues: ethical and legal issues* (1995); *Animal-to-human transplants: the ethics of xenotransplantation* (1996); and *Mental disorders and genetics: the ethical context* (1998); and will produce a Report on *Genetically modified crops: the ethical and social issues* in the late Spring of 1999. In addition, the Council will this year host Workshops on the Ethical Issues of Clinical Research in Developing Countries and Patenting Life Forms. (The current membership of the Council appears at Annex 1).

The Review: Two Central Questions

The Council welcomes the Government's decision to review the framework for overseeing developments in biotechnology. We would caution, however, that our experience with our terms of reference is that it is not always possible to draw a clear line between biomedicine and biotechnology. Indeed, to separate out biotechnology as some free standing subject area presents at least the risk that interactions with other areas of development may be overlooked.

That said, we regard it as extremely useful for government to take stock of the process by which it seeks and receives advice on developments in biotechnology. Fundamentally, we see the Review as being concerned with two questions. The first is, what issues require consideration. The second is, by whom should they be considered: should they be reviewed within government (in-house), or outside by some independent body and,

if so, how should this body be constituted. In this response, we will address these questions and some of the other particular issues raised in the Consultation Document, reflecting the Council's perspective and drawing on our experience.

An Independent Overseeing Body

In broad terms, the Council recognises the need for, and value of, analysis and advice from inside and outside government. The Council sits outside government. Our primary focus is on ethics, but given our engagement with policy making, we are also concerned with and have experience of a number of the other issues raised in the Consultation Document. Our experience leads us to believe that, whatever other mechanisms there may be for overseeing developments in biotechnology, there is considerable value in the existence of a body such as the Council which is independent of government and industry and which is able to inform, educate, offer advice, and assist in the formulation of public policy, across the whole sweep of developments in biotechnology (and related biomedicine).

To an extent, the Council currently plays a similar role. Thus, in describing the nature and purpose of this independent body, to some extent we describe ourselves. It follows that the Council would be prepared to meet this need, to the extent which government thinks appropriate.

The proposed broadly based body, outside government would be charged with an overarching responsibility to advise on developments in biotechnology (and related biomedical issues). It would complement any framework for advice set up within and across government. The body could only function effectively, however, and thereby be of service to policy makers and retain public confidence, if its remit was carefully drawn. One single body could not purport responsibly to offer considered advice across the whole range of issues in biotechnology. Indeed, it would command little confidence if it attempted to do so. And, the gaining and retaining of public confidence would have to be a central responsibility of the body, given the public unease over developments in biotechnology and the consequent threat of distorting policy making and deleteriously affecting research and development. Thus, any single, overarching body would have to work through appropriately constituted and designated sub-groups. The benefits of the current framework could be retained if many of the current ad hoc groupings could be reconstituted as sub-groups of the "parent" body with one or more members of the "parent" group sitting on any particular sub-group.

That said, it would be important that any new overarching body should be given a limited and clearly prescribed range of tasks. These would include:

- coordination—managing and bringing together the work of sub-groups, and others;
- oversight—monitoring and reporting on the work of sub-groups, and others;
- foresight—scanning the horizon;
- anticipatory review—analysing imminent developments and advising on them.

The body would exist to provide rigorous analysis. In its foresight role, by examining issues in advance of their incorporation into practice, for example, it would seek to alert and therefore prepare policy-makers, rather than be forever engaged in making instant responses to events as they occur. Furthermore, it is essential that certain other tasks, important as they are to the process of managing any response to biotechnology, should be dealt with elsewhere. In particular, regulatory, monitoring and administrative matters should be devolved to appropriate purpose-built agencies, which can marshall the necessary but different expertise.

The transition to such a system would not be as disruptive as beginning again from scratch. But, at the same time, the creation of this new element to the framework would allow the opportunity to rethink some of the current ad hoc arrangements, re-draw existing boundaries and rationalise terms of reference, membership and, most importantly, secretariat. Thus, savings could be made in personnel and resources to offset any cost of creating an additional, broadly based body. It would also, crucially, serve to reassure the public that there is some single, responsible and accountable body which is surveying and advising on the whole scene ("the big picture" as it has been described). At the same time it would serve to reassure government that a mechanism of coordination and oversight existed to bring together the various opinions and recommendations emanating from the various ad hoc groups.

The form of any overarching body would need careful discussion. The Council considers that whatever form it takes, certain key conditions would have to be met. First, as has been said, it should be independent of government. The advantages are numerous and only three are mentioned here: its independence would enhance public confidence in the advice it tendered, particularly in areas (such as genetically modified crops) in which suspicions abound. In addition, its findings and advice would be deniable, given its arms-length relationship with government. It is crucial for government to have this option since even the best informed group of expert advisers cannot be aware of all the political implications of certain decisions. Furthermore, its status as an independent and centrally important body would mean that it would have access to the best expertise available. Second, the membership should not be too large, (the US model (16 members) being preferable to the French (40 members)) and should bring a variety of expertise, including, particularly, the views of the non-specialist or layperson.

The Current System: Overlaps and Gaps

We turn to some of the issues specifically raised in the Consultation Document. As regards the existence of overlaps and gaps, the present system for the review of biotechnology involves a multiplicity of bodies with widely varying remits. Clearly, there are advantages in such an approach, deriving from its thoroughness and ability to call upon a wide pool of expertise. There are, however, a number of disadvantages. The first is the most obvious. As each of the bodies comes to define its area of activity, it does so with particular reference to its resources and current competence. The danger arises that issues which cross the boundaries which have been drawn or fall to some degree outside any particular boundary will be missed, for example on the assumption that others elsewhere are examining them, or will not receive the necessary attention, being judged peripheral to the main enterprise. A second danger is that, in any field in which expertise is limited, there will be a very considerable duplication of effort, both on the part of those advising and, perhaps more important, the supporting secretariat. This involves a very real waste of scarce human resources and a concomitant cost. In the case of secretariat, it argues for the consolidation of civil service support into something akin to a specialist biotechnology grouping or Directorate. Thirdly, the current system of overlapping, subject-specific bodies militates against the possibility of any of these bodies being able to take, or taking responsibility for scanning the horizon for issues about to emerge. Each body becomes consumed by its specific task. This "silo" effect is well known in government and has given rise to recent moves to develop and enhance cross-government initiatives and action. Taken together, these various drawbacks may be seen as strengthening the case for some sort of co-ordinating body.

Ethical and Other Wider Issues

The Consultation Document then asks whether ethical and other wider issues are fully and properly addressed under the present system. There can be no doubt that one of the major functions of any framework devised to review developments in biotechnology must be to advise on the ethical, social, financial and legal implications. These tend to be interrelated and often need to be disentangled. Of particular concern to us are the ethical implications. Indeed, some have predicted that the next century will be the century of bioethics as societies grapple both with the moral implications of biotechnological developments in, for example, genetics and the neurosciences, and with the concomitant anxieties and concerns of a public not always well-served by existing means of disseminating information and promoting understanding.

Ethical analysis must be rigorous and is often complex, subtle and difficult. It is not about looking for or gaining consensus, nor necessarily some comfortable welfarism. While it can be said that the level of ethical debate concerning developments in biotechnology has generally been high in the UK, there have been occasions when it has come too late and been confined within an agenda set by the tabloid press. On other occasions it has seemed too remote from the concerns and sentiments of the public. Information and ideas can be passed on to the public in an accessible manner without losing intellectual rigour. It is not compulsory to be unintelligible in order to be profound! Furthermore, and this is crucial in terms of how any review body interacts with government, ethical analysis is not about "instant comment" on "hot issues" as they arise in the press and elsewhere.

To an extent, of course, emerging issues will have been identified in advance and advice offered in anticipation. On occasions when this may not occur, the example of the response to cloning in the USA is instructive. Confronted by the apparently dramatic development of cloning, and florid comments in the media, President Clinton was able to refer the issue to his National Bioethics Advisory Commission (NBAC) and request that it report within 60 days, which it duly did. The benefits were obvious. Instant comment by government was avoided, government could properly claim to have acted (by referring the issue to the NBAC) and the NBAC could deliberate carefully, drawing on its expertise, to produce a considered and well-reasoned document setting out policy options for government. Such flexibility of response may not always be available to the UK government, not least on issues which transcend, or do not fall naturally within, the boundaries of current ad hoc groups.

Public Confidence and Transparency

The public confidence in any system of providing advice for government is increasingly related to the system's transparency. Such transparency can be achieved through formal mechanisms. It can also be achieved, and in perhaps a more lasting and effective fashion, through the style adopted in offering advice or seeking to promote understanding. As for formal mechanisms, clearly modern information technology allows material to be assessed and brought into the home. It follows that as much information as possible should be accessible through, for instance, dedicated web-sites. Reports, work in progress, discussion papers, agenda and minutes are obvious candidates, but databases of, for example, regulatory frameworks in the UK, EU and elsewhere, or of biotechnology work in progress are equally possible. As for other ways of enhancing transparency, they interact, as has been said, with measures aimed at ensuring public confidence. Meetings held in public at different locations, or on the Internet would be one such way. Another would be to involve the public and seek their opinion, through whatever consultation process was deemed appropriate, both early on and at various stages thereafter of any deliberative process. Any such consultation must be through some sensible and valid approach, rather than, for example, some pursuit of an often illusory consensus. Nor

should it be assumed that public "reassurance" must always be the goal of public understanding. False reassurance, apart from being wrong, causes much more harm in the long run, as recent experience with BSE illustrates.

The common pattern of public involvement currently is to present the public with a finished Report, tacked on to which is a consultation exercise which has the appearance, if not the reality, of being a formality. The impression created, where impression is all-important, is one of experts talking to experts, or to government, with the concerns and interests of the wider community receiving less than careful attention. From this grows public disquiet and distrust. The public may feel that no-one listens while those with vested interests may quietly lobby behind the scenes. A further advantage of involving the public at an earlier stage and regularly thereafter is that it would help to prevent one of the greatest impediments to discussion of developments in biotechnology. This is that issues, by the time they are aired in public, are often represented in the form of a bi-polar contest. It may be argued that the current system of ad hoc groups may add to this by consulting the public only at the stage when a yes or no answer is sought on a particular issue. Greater involvement of the public, not least through imaginative use of the school curriculum, could deconstruct this contest and present issues in a more subtle and measured manner. Furthermore, a strategy aimed at refocusing the way in which biotechnological developments are presented in the popular press is urgently needed. We have already referred to the bi-polar and, to a degree, sensationalised reporting which bedevils this area. Periodic briefings of editors by an independent body would go some way to introducing the media to such concepts as relative risk, and in advancing their general understanding of the complexity of issues. While it may only slowly affect reporting, it will make it more difficult to advance the extremes of opinion which often currently pass for debate.

SUMMARY

The Council:

1. commends the Review and its timeliness;

2. suggests that the two fundamental questions to be addressed are, what government needs advice on and from whom it should be obtained: in particular, the respective roles of groups within and independent of government;

3. draws attention to disadvantages, as well as to advantages, in the current framework of ad hoc groups;

4. suggests the desirability of some overarching, co-ordinating body, not least because of its independence and the twin advantages which flow from this, public confidence and deniability by government;

5. suggests that strategies to gain and enhance public confidence in developments in biotechnology, must include better efforts to involve the public, and at an earlier stage, and should take full account of the opportunities provided by information technology and

6. draws attention to its experience and expertise in evaluating the ethical, social and legal implications of developments in biotechnology and biomedicine and offers its assistance to government in whatever role may be deemed appropriate.

February 1999

APPENDIX 7

Memorandum submitted by Green Alliance

INTRODUCTION

Green Alliance is one of the UK's leading environmental policy organisations. It works to ensure that the environment is a prime consideration in commercial and political decision-making.

Green Alliance has been a commentator on biotechnology policy since 1987. Since 1990, Julie Hill, former Director and now Programme Adviser to Green Alliance, has been a member of the Advisory Committee on Releases to the Environment (ACRE). She is also presently acting as an adviser to the Office of Science and Technology on the Public Consultation on the Biosciences, and to the Nuffield Foundation on Bioethics on a report on the ethical implications of genetically modified plants. Green Alliance has been responsible for a series of seminars and debates on biotechnology policy involving a wide range of interest groups, including environment and consumer groups, regulators, scientific advisers and companies.

Green Alliance's experience of biotechnology policy is mainly related to the agricultural applications of the technology, and the possible environmental impacts of those applications. The committees with which we have most concern, and are most familiar, are therefore the Advisory Committee on Releases to the Environment (ACRE), the Advisory Committee on Genetic Modification (ACGM), the Advisory Committee on Novel Foods and Processes (ACNFP), and the Advisory Committee on Pesticides (ACP).

1. *The adequacy and quality of scientific advice at present*

The issue of "adequacy" of scientific advice is, in our view, mainly linked to the remits of the committees and the way in which these seek to ensure environmental protection. There has been widespread criticism that ACRE's remit has been too narrowly drawn, concentrating primarily on what are thought to be the "direct" effects of genetic modification (GM), ie the impact on the environment of genetically modified organisms (GMOs) in themselves, or the flow of genes from GM crops to wild relatives. "Indirect" and cumulative effects have been neglected. These effects include the possible environmental consequences of changes to agricultural practice facilitated by GMOs, ie changes to chemical regimes as a result of developments such as herbicide tolerance, changes to the types of crops grown, or changes to rotational practice.

It is only recently, with Mr Meacher's Parliamentary answer in November 1998, that "indirect" effects have been acknowledged as an important part of environmental risk assessment and as part of ACRE's remit. This extension of ACRE's remit was followed in February 1999 by the publication of an ACRE/DETR paper on the possible impacts of GMOs on wildlife[1], and the establishment of a technical sub-group of ACRE to consider how to incorporate these considerations in the Committee's risk assessment procedures.

The above steps are important and welcome. The important questions now for Ministers, for ACRE, and for the ACRE secretariat in DETR are:

(a) Does ACRE have the right membership, in terms of types and level of expertise, to give sound expert advice on "indirect" effects? (The majority of ACRE's membership will change in June 1999 giving an opportunity to expand the expertise available, and recruitment is now underway).

(b) How will ACRE develop protocols for assessing indirect effects that command widespread credibility among all the interested parties, ie the Government, the Government's statutory nature conservation advisers, environmental groups, and the companies developing and using the technology? Does ACRE have the means to secure input to, and ownership of, the protocols from all these groups?

(c) Is the Government's new policy of excluding direct employees of environmental groups from membership of ACRE likely to be a help or a hindrance to this process of securing ownership for ACRE's new remit?

(d) Do ACRE and DETR have sufficient mechanisms for liaison with MAFF and the ACP to ensure that work on assessing the environmental impacts of the pesticides used in conjunction with GM crops is complementary, and not conflicting?

Another important aspect of "quality" of scientific advice is to acknowledge what is unknown as well as what is known. Another major criticism of both ACRE and ACNFP has been that insufficient prominence has been given to the scientific uncertainties inherent in risk assessment. The committees' advice should more explicitly acknowledge those areas where there is a lack of relevant scientific data to draw firm conclusions. The long-term health impacts of the use of antibiotic resistance genes and the long-term ecological impacts of the spread of herbicide tolerance genes are two recent examples where advice has had to be given in the face of considerable gaps in scientific knowledge.

It is also important for scientific advice to be clear about which questions are ones of scientific knowledge, and which are more value judgements—the "does it matter" questions. Again, ACRE's recent deliberations about the possible spread of herbicide tolerance genes from oilseed rape to wild relatives provides a good example. Science can provide some data as to the likelihood of geneflow, but opinions differ as whether the "contamination" of wild species by introduced genes should be regarded as a problem or not. To some people it is only a problem if it has tangible deleterious consequences; to others it is an unacceptable "genetic pollution", whatever the consequences. The "does it matter" questions are best moved away from the committees giving scientific advice to the political level, where a more broad-ranging debate should be possible.

2. *The role and framework of advisory committees*

The most important point about the "role" of scientific advisory committees is that they should be seen as part of the advice available to Ministers on GMOs, and not as the only component of that advice. Recent Government statements, particularly by the Prime Minister, have emphasised the Government's heavy reliance on scientific advice and the overwhelming importance given to the concept of "sound science". This is no longer a credible stance. The public at large now has a sense of the breadth and complexity of the issues raised by GMOs, and a sense that science alone might not provide all the answers. In particular, as outlined above, scientific advisers are not necessarily qualified to take on some of the important value judgements raised by GMOs. The Government has to be able to demonstrate that it is drawing advice from a range of bodies and sources outside the scientific advisory committees.

It follows from the above that the "framework" of the advisory committees needs to be augmented by bodies that are capable of taking a strategic view. A strategic view of all the ways in which GM technology

[1] The Commercial Use of Genetically Modified Crops in the United Kingdom: the Potential Wider Impact on Farmland Wildlife. A discussion paper prepared by the Secretariat to the Advisory Committee on Releases to the Environment, February 1999.

might affect the environment, both positively and negatively, has so far been lacking. A strategic view could also usefully embrace all the implications for food and health of the use of GM in agriculture and food production. Such a strategic view needs to develop at pan-Governmental level, so that it involves all the relevant Government departments.

A useful start towards such a strategic view, although probably not sufficient in itself, would be the establishment of a body to co-ordinate the procedures and practices of the scientific advisory committees. Such co-ordination would have the aim of ensuring that there are no gaps in the coverage of the risk issues associated with GM, and that the committees work to consistent risk assessment methodologies, common standards for appointment of members, and common standards of transparency. The co-ordination body should include the chairs of the relevant committees, but should also incorporate outside expertise, and work to standards of maximum transparency.

Another gap has been any structured means of incorporating stakeholder interests into decision-making. The reason for trying to incorporate the views of stakeholders (companies, environment and consumer groups, regulators, scientific opinion) is to work towards a consensus view of the possible problems associated with using GM technology, and then develop widespread ownership of the solutions. Again, this is certainly needed for the environmental implications, and could usefully be extended to food and health implications.

Wider than "stakeholder" interests are the values and concerns of members of the public, which also need to find a voice in decision-making. These are not straightforward to assess and incorporate, but work in progress by the Office of Science and Technology[2] and the Nuffield Council on Bioethics[3] should help to shed further light on public attitudes. It is already clear that people at large have a mixture of concerns rooted in principle, and concerns connected to the consequences of the technology, but all these concerns are in the end "ethical"—they are about whether we are acting properly in allowing the technology to proceed. To take account of the public's ethical reactions, the framework of scientific advice needs to be complemented by the development of a set of ethical standards for the deployment of GM technology within which all policy and regulation is framed. These standards would have ownership from the companies developing and using the technology as well as from the Government. A high level body is needed to develop and implement these standards.

3. *The ability of the current system to respond to rapid scientific developments*

The present advisory system is limited by the predominance of the "case-by-case" approach to risk assessment, which makes it difficult to look ahead at GM developments and take a strategic view of their impacts. As described above, such a strategic view needs to take place in a separate forum from the individual committees, although with their input. However, the individual committees should consider how they can develop mechanisms for periodic "foresight" about the kind of scientific judgements they might have to make in future. This might most effectively be done through structured discussions with the companies developing the technology.

4. *To what extent is there value in the proposal for an overarching body to advise on and oversee all genetically modified food issues*

There is considerable value to the idea of an "overarching" body, if what is meant by that is the need for a body to take a more strategic view of GM development. As outlined under Q2 above, Green Alliance has identified a number of ways in which the current framework of advice needs to be augmented—by the ability to take a strategic view, at least of environmental impacts, and usefully of food and health implications as well; by better co-ordination of the work of the current scientific advisory committees; by a mechanism to incorporate "stakeholder" interests into decision-making; and by a set of ethical standards to more fully incorporate the values of concerns of a wider public. Ministers will need to consider how far any one new body could take on all these tasks, or whether a suite of new institutional approaches is needed.

5. *The capacity of Government to be an "intelligent customer" for the advice it receives*

In the view of Green Alliance, being an "intelligent customer" means the Government acknowledging that scientific advice is not the only kind of relevant advice, or necessarily the most salient. Much depends on the nature of the questions being asked—whether they are questions of the nature, extent, or acceptability of risks—and the Government needs to be discriminating about how far any of these can be answered by particular types of expertise or opinion. In particular, the Government needs to keep itself appraised of the risk assessment methodologies and assumptions being employed by scientific advisory committees, so as to be aware of the limitations of the science.

Most importantly, the Government needs to take responsibility for the final decisions made, whether on GMO policy in the round, or on individual applications. The Government is good at giving the impression that it is bound to take the advice of its scientific advisory committees, which is legally not the case, although

[2] Office of Science and Technology Public Consultation on the Biosciences.

[3] Nuffield Council on Bioethics Working Party on the Genetic Modification of Crops.

it should, of course, justify what else has been taken into account and why it has rejected certain advice. It is crucial that the Government demonstrate that it is capable of seeing scientific advice in a much wider social context.

March 1999

APPENDIX 8

Memorandum submitted by Sheffield Institute of Biotechnological Law and Ethics (SIBLE)

INTRODUCTION SIBLE

(a) The Sheffield Institute of Biotechnological Law and Ethics has been involved in advising on legal systems for the assurance of safety in relation to biotechnology for many years. It was set up to enable the expertise of many individuals within the University of Sheffield, relating to the ethical and legal issues that dictate the manner in which this new technology may be used, to be harnessed. The Institute defines Biotechnology extremely widely, including the use and introduction of genetically modified organisms into the environment and the food chain and the use of the technology within medicine. Biosafety and its regulation have formed a major plank in its work, as have intellectual property rights (including plant variety rights) and the need to consider ethical principles in the adoption of modern biotechnology to industry, agriculture, food and medicine.

(b) There is a need at the outset to declare an interest, since Dr Julian Kinderlerer, Assistant Director of SIBLE, who is the person in SIBLE most involved with the issues surrounding genetically modified food, has been a member of the Advisory Committee on Genetic Modification (ACGM) since its formation in 1984 and also of ACGM's technical sub-committee. He was also a member of the predecessor of the Advisory Committee on Releases into the Environment, ACRE during the 1980s—the Intentional Introduction Sub-committee of ACGM—and has been a member of ACRE since its foundation in the early 1990s. He has also served as a member of the Microbiological Risk Assessment Working Group of the Advisory Committee on Dangerous Pathogens. In addition, he has helped to set up the regulatory system in many other countries, including the Russian Federation, Bulgaria, Czech Republic, Thailand, Malaysia, South Africa, Namibia, Mexico and Brazil through work with the UNIDO and UNEP. The respect in the international community for the layered system we have set up in the UK needs to be acknowledged. While aware that the European System for oversight of biotechnology would seem to be failing, that instituted in the United Kingdom has been copied by many, and we are often surprised how much of what is written for the guidance of those using the technology here in Britain appears in official papers in other countries.

(c) Dr. Kinderlerer was the specialist adviser to the House of Lords Select Committee on European Legislation, Sub-committee D (Agriculture and Food) during its investigation into the regulatory system on Genetically Modified Food and Agriculture during 1998. The report was published on 21 January 1999. The comments that follow are provided by Dr Kinderlerer.

SUMMARY

1. *Scientific Advice*

1.1. The approach taken to assessing the production and release of Genetically Modified Foods and Feeds has been to require a risk assessment (in relation to both human health and impact on the environment) of those intending the release, and the Advisory Committees have performed an audit role in assuring Government of the adequacy and completeness of the assessment. The principles used in the risk assessments have been based on those adopted by the OECD as early as 1986, and on the European Directives produced during 1990 (90/219/EC and 90/220/EC). It was only in 1997 that the Novel Foods Regulation (258/97) changed the process so that the Advisory Committee on Novel Foods and Processes has the responsibility to advise on a risk assessment on the basis of information provided by the applicant. There is a problem in that the different member countries of the European Union have interpreted the principles under which they work very differently.

1.2 The range of expertise and experience that is needed to assess the risks associated with the use of a new technology makes it difficult to set up a system that is able fully to assess the impact of the introduction of products into the environment without involving expertise from outside Government Departments. The United States does not use an Advisory System, preferring to use the expertise of those employed by the various Agencies when considering individual applications for the commercialisation of a new product.

1.3. The advice provided by the Committees has attempted to take the best scientific information that is available on a vast range of topics. It has been seen to be important that not only is the advice theoretically accurate, but also that it considers the practicality of achieving a particular goal. It has, therefore, involved scientists who know as much as possible about the issues, non-scientists who are able to bring the scientists down to earth, and individuals who are or have been employed in the industry to ensure the practicability of risk management procedures.

1.4. There is a problem in providing advice, in that many of the risks are not easily quantifiable. They may be very high hazard but this may have a very low probability of being realised. There is often little or no information on which to base the assessments. The "precautionary principle" has been adopted, not to prohibit that about which little is known, but rather to proceed with care and caution. It has been interpreted in the UK as requiring a step-by-step and case-by-case approach. Each step in the approach to commercialisation of a new product has been considered by an Advisory Committee that has then advised the applicant and government on whether the management procedures that the applicant intends to take are adequate and whether any other procedures are needed to safeguard the health and safety of people and the environment. What has not been done is to indicate to the applicant the information needed from the current "experiment" before the next stage will be allowed to proceed. Each stage is considered in the light of the information provided (which will of course require evidence from previous experiments).

2. *The role and framework of Advisory Committees*

2.1 Advice on each case should primarily lie within the ambit of expert advisory committees which either perform a risk assessment on data provided by the applicant wishing to use a modified organism (such as done by ACNFP) or audit a risk assessment performed by the applicant (ACRE, ACGM). Although expert committees have been challenged as to their independence, it is difficult to see how any committee performing a risk assessment or auditing one already done could consist of other than experts in the field, who perforce cannot be totally independent. Whether the case-by-case analysis should be done by sub-committees or free-standing committees is not an issue: there must be a mechanism for achieving the careful analysis of that proposed. ACGM has set up a technical sub-committee that is a separate committee in all but name, sharing fewer joint members than many of the other separate committees. ACGM itself does not attempt any case-by-case examinations of proposals, delegating these to its sub-committee. All the other committees, on the other hand, do the case-by-case analysis themselves. This reflects the change in the science over the last 20 years, where most of the need for the detailed review of applications falls within the remit of ACRE and the food committees. During the 1980s ACGM had only to consider human health and safety. Risk assessments now have to consider the possible impact on the environment of the use of modified organisms.

2.2 ACRE's remit in the past was interpreted extremely narrowly. Although the need for the Committee was recognised in the Environment Protection Act, 1990, neither its composition nor remit were detailed in the Act. The Committee was therefore surprised when, at its first meeting following the coming into force of the new law, it was discovered that its remit had been narrowed significantly from that which it had assumed when working on a voluntary basis.

2.3 Initially the work of the Committee was primarily related to experimental releases of transgenic organisms (mainly plants) in very small plots. The case-by-case analysis could, therefore, be based on the need to consider that case, in relation to all evidence including that of previous experiments, but with no requirement to consider other crops or changes to farming practice or any considerations outside the narrow confines of the experimental details. This approach was questioned by some members of the Committee at the time, but was justified given the scale and experimental nature of the work. It was also seen that many of those issues identified as wider were really the responsibility of the Ministry of Agriculture rather than of a committee which had specific responsibility for looking at the safety of transgenic organisms relative to unmodified organisms within the particular environment.

2.4 The narrowness of the remit continued into the Committee's analysis of applications for commercialisation of crop plants, although expressed differently. Here the Committee has largely limited its consideration to the release of the crops within the United Kingdom, and their impact on the UK environment. It has assumed that the impact on other environments (Southern France, Spain or Italy, with different climates) has been left to the responsible competent Authorities. Obviously, for food use, the impact on human or animal health of eating a modified organism was considered regardless of climate.

2.5 Hence, although the holes in the regulatory structure are likely to be smaller than those in the United States, where the Agencies are rigidly separate, there have been holes in the regulatory oversight. In particular, the Advisory Committee failed to address the likely impact on farming practice, or the impact on wildlife because of these changes.

2.6 The Advisory Committee on Novel Foods and Processes (ACNFP) is non-statutory, but has had an enviable reputation for its careful analysis of each new food it has been asked to consider, and for taking up many of the major general issues in a very detailed way. The paper produced by ACNFP on antibiotic resistance markers is considered a model for the manner in which a novel process is analysed and opened for public debate. The Committee has had a new role since the coming into force of the Novel Foods Regulation in 1997, but it is too early to judge its ability to meet the new remit.

2.7 ACRE and ACNFP have very different roles and therefore interpret submitted data differently. Where the Committees disagree, that disagreement is made public, and the Minister has to decide which advice to accept. In every case, the Minister has accepted the advice, which means that the UK position is to not allow the use of that particular GMO.

2.8 There are many other committees which have a role to play in deciding on the use of GMOs in the environment. If a GMO contains a pesticide, then there should be an examination of the efficacy of that

pesticide and the likely impact of the pesticide on the environment. This could be performed by ACRE, but much of the expertise must lie within the Advisory Committee on Pesticides. Should a GMO be designed in order to produce pharmaceutically active products, the impact on the environment is an issue, but so is the likely effect on workers, and there will be a need for committees in the medical area to join in the assessment.

2.9 In almost all cases, therefore, the assessments are currently case-by-case, and in most circumstances, the wider impact of a particular product is not easily considered by the current structure.

3. *Overarching Committee?*

3.1 I believe that there is a need for a committee that has a specific brief to consider the interaction between genetically modified crops, the natural and agricultural environment and agricultural practice. It should not consider individual applications for release, nor issues that fall directly within the remit of the other committees. It seems to me that the brief should include wide consultation on general issues with all interested "stakeholders", and a mechanism to feed the results of these consultations (and the advice of the Committee) to the committees which take decisions on individual applications. This new committee could respond to referrals from any of the committees whose work impinges on this area, refer specific issues to appropriate committees and respond to ministers on any issues of wider import to the application of the technology. It would reduce the size of the hole that I, as an insider, have perceived for some time.

4. *Other Issues*

4.1 Much of the rest of that which I would have liked to write about in this response to the Committee is contained in the report of the House of Lords Select Committee for which I was privileged to assist.

10 March 1999

APPENDIX 9

Letter to the Clerk of the Committee from the Natural Law Party

The BBC's reports of statements by the Monsanto representative to your committee yesterday were entirely at variance with our experience.

We belong to an organisation which has for a long time been campaigning to disseminate correct information about genetic manipulation of foods to the public. Seminars and conferences we have held and participated in on the topic are almost never attended by members of the biotech industry.

According to the BBC, Anne Foster stated that they participated in conferences whenever possible. For our part, we can definitely say from the experience of organisations up and down the country that this is not the case. For example, this Tuesday, at University College, London, in the second of a series of five seminars being held this week, Monsanto sent one brochure instead of the speaker they had promised and who was on the programme to speak. Similarly, no one from the industry showed up at the Wednesday night conference at Imperial College.

If these were isolated cases, we would not bother to inform your committee, but it is an endemic characteristic of the biotech industry that they offer poorly researched information, or half truths, instead of the full facts. It is inappropriate for the industry to claim they participate "whenever possible", when they avoid seminars and debates like these.

10 March 1999

APPENDIX 10

Memorandum submitted by Novartis

INTRODUCTION

Novartis welcomes the opportunity to respond to the Science and Technology Committee's case study examining the issues surrounding scientific advice to Government regarding genetically modified (GM) foods.

To date, Novartis' experience of the UK system dealing with GM food and crops relate to regulatory approval on:

Bt-maize approved for importation, processing and cultivation in the European community. In the UK Bt-maize is approved for import and use in human food and animal feed. Cultivation of the presently approved Bt-maize strains is not envisaged in the UK where the European corn borer, which Bt-maize has been modified to protect itself against, is not a pest of the crop.

Development and trialling of herbicide-tolerant sugar beet.

Development and trialling of genetically modified wheat.

Our observations are based upon our interaction primarily with ACRE and ACNFP in the course of this regulatory process. These are the two committees with which we have enough experience to give a solid judgement. Novartis employees have not been members of these committees and have not been involved in advising Government through these committees.

The progress in recent years in the fields of molecular biology, plant physiology and genetics is of tremendous significance for the future of agriculture. The guiding principle of our agricultural research and development is to fully explore these new approaches for the benefit of our customers, the public and the environment and to harness progress for the benefits of society as a whole.

We welcome the opportunity for more openness and balance in discussing GM crops. We recognise there are concerns, whether real or perceived, regarding this technology which must be addressed. Government's priorities are human safety and protection of the environment through a system of rigorous assessment and regulation. The Committee's case study, by focusing on the scientific advice given to Government on GM food and crops, provides a real opportunity to shed more light on the debate.

1. *Adequacy and quality of scientific advice at present*

1.1 Novartis welcomes and requires a clear, transparent and science-based regulatory framework in the UK, compatible with international legislation. Such regulation protecting and promoting public health and protecting the environment is an essential element of successful scientific development. This regulation must respond to scientific advances with consistency. The Treaty of Rome contains various principles which underpin regulation and should underpin the UK's regulatory framework for biotechnology.

1.2 As a multinational company, interacting with regulators and government scientific advisors all over the world, in our experience, the quality of the scientific advice given by ACRE and ACNFP to the British Government is amongst the best in the world.

1.3 We believe this quality of advice has been achieved through use of the best expertise in the country to give advice in an open, transparent and responsive manner. The specific expertise and experience on the key areas of GM food regulation—genetic modification and human health effects, plant technology, sustainable agriculture and environmental biodiversity, and other relevant areas—represented on the committees, is of a very high calibre.

1.4 The quality also comes from each of these committee members making professional judgements with independence and integrity. There has been much public questioning of the independence and therefore credibility of committee members who have links with industry. In our experience, there are no grounds for these accusations. Scrutiny of potential "vested interests" at play should be applied to all members.

1.5 Advisory committee members are drawn from leading independent specialist centres as well as the biotechnology industry. When a committee member is from industry, it is openly declared and it is common practice for a committee member to be omitted from discussion and decision-making in areas where they have declared an interest. Biotechnology is a comparatively young area of science and therefore there are a limited number of sources for this expertise. A certain amount of this resides within companies at the forefront of developing this technology. This trend and practice is also seen in other European Member States.

1.6 A scientific advisory system should give advice based on science. It is vital that the committees have sufficient expertise and experience of the specialist science and agricultural areas involved in GM food/crops. However, in this debate, other issues have been confused with product safety and science. For example, segregation concerns consumer information and choice but is not about science. There is obviously a need to address consumer acceptance but there should be a clear distinction between regulatory and ethical issues.

2. *The role and framework of advisory committees*

2.1 The role of Government advisory committees in this area is not to undertake risk assessment but to do an audit, and provide an independent evaluation of the quality of the risk assessments submitted by industry. By delivering this quality control, they guarantee that the right questions have been asked, and that the answers are the best that science can give.

2.2 There is a feeling in some circles that it is a flaw to rely upon product risk assessment data generated by companies and that this should be undertaken either by the advisory committees or through some other independent means.

2.3 Risk assessment data in GM crops and in other areas of technology is extremely expensive to develop and takes a considerable amount of time to produce. Companies in all areas of science are responsible for generating the risk assessment data for their own products. They also go into the risk assessment process with the best knowledge of their products, and a lot of highly specialised expertise. It is extremely difficult for a regulatory body to bring together the necessary expertise to do a risk evaluation on each individual product, as the questions are different. This is why it is more effective if the regulatory advisory bodies function as "examiners" of the quality of the risk assessment work done by the companies.

2.4 Novartis is a world leader in the amount we invest in R&D every year, and over long timescales. A company like Novartis, building a long-term sustainable business, with a heritage of safe and successful products based on good quality research and development (R&D), has a real vested interest in ensuring products are safe and effective. So much is at stake if we get it wrong.

2.5 Once a risk assessment has been completed, it is the job of advisory committees to examine that data, ensuring that the right questions have been asked and answered satisfactorily. It is also quite clearly in their remit, to request additional information from applicants if they feel there is insufficient data. In our experience, ACRE and ACNFP are extremely rigorous and thorough in their examination and analysis, ensuring that the advice given to Government results in the protection of health and the environment first and foremost.

2.6 This system, whereby commercial companies generate the risk assessment data which is then reviewed by independent bodies, is common to a number of industries—eg pharmaceutical registration, crop protection chemistry—and appears to work well.

2.7 The current framework covers the development of applications of biotechnology in agriculture and food safety. It is accepted that Government decisions on biotechnology regulation emanate from the advice of a number of advisory committees and that areas of overlap occur to ensure complementary decision-making rather than duplication.

2.8 The United Kingdom is fairly unique in that each of the committees have their own specific role that is complementary to one another ie one applying EU Directive 90/220 (concerning release of GMOs into the environment) and one applying the Novel Food Directive. This is not the case in several other EU member states where there is considerable overlap.

2.9 The current roles and complementary working of ACRE and ACNFP ensures that all the relevant products of biotechnological research in the agricultural field, for example our own herbicide-tolerant sugar beet, will be looked at from the two perspectives of environmental and novel food safety.

2.10 We welcome the broadening of the role of the advisory committees to research the positive impact of field scale biotechnology on the wider agricultural landscape and wildlife in our country. However, this initiative which we believe to be so important and support fully should not synergise with current or future 90/220 regulations and should not be seen as an opportunity to overburden the technology with hurdles that are too high to overcome.

2.11 The Government is committed to addressing consumer concerns and is becoming more transparent by openly providing information about the agenda and the meetings of the advisory committees. Some of the advisory committees comprise a consumer representative, further evidence that the views of the public are being represented on the committees and therefore being heard by the Government. We welcome the fact that consumer viewpoints are being considered but we query whether these broader questions should be considered in the current mechanism which deals essentially with scientific risk assessment on a case-by-case basis.

2.12 We suggest that Government considers including a process auditor of an independent nature in each stage of the process, to comment and validate the rigor, application and completeness of the committee process itself, whilst the scientific details would be left to the appointed experts.

2.13 The UK system fits into a broader framework of European regulation of biotechnology. For example, the advice provided by some UK committees represent national implementation of EU regulation (eg EU Directive 90/220 is implemented by ACRE).

3. *Ability of the current system to respond to rapid scientific developments*

3.1 It is our belief that the committees are able to respond effectively and in a timely manner to give proper scientific advice to Government on rapid scientific developments.

3.2 The committees are not equipped to respond to the sort of media pressure that is generated around incidents such as the story of Dr Pusztai and it is questionable whether this rapid response to media viewpoints should fall within their remit.

3.3 The whole story around Dr Arpad Pusztai's research serves to emphasise that sound scientific advice is based on scientists being able to critique published, peer-reviewed data and not through media headlines.

3.4 The current system has been criticised for not taking into account broader views about GM food and crops eg wider social and political considerations. Government clearly needs to take this broader context into account, but these issues are not inherently science-based and need to be dealt with separately from the science.

3.5 The EU regulatory process is in a gridlock. For example, applications under EU directive 90/220 have missed agreed time limits and the process has almost ground to a halt due to an inability of the EU to make decisions. Our concern is that this may impact on the UK regulatory processes in the near future unless the whole European framework is restructured and simplified.

3.6 The UK is a leader in biotechnology development and there is strong knowledge and expertise to continue to build upon. We therefore look to the UK Government to ensure that the current system continues to respond effectively and rapidly to scientific developments.

3.7 The public is not confident that its interests are sufficiently represented in this process and proactive communications about the regulatory system in place is key. Any improvements to the system should incorporate communications to the public as a major priority. This communications strategy would need to be consistent across all relevant Government departments.

4. *To what extent there is value in the proposal for an overarching body*

4.1 The current committees (ACGM, ACRE, ACNFP) together consider the total biosafety impact of each individual GM crops/food covering their safety for human consumption, the impact on animal health and environmental risk assessment.

4.2 There are two dimensions in which there could be integration through an overarching body, and it is important to clearly distinguish them:

4.2.1 Integration of the current scientific advisory bodies on biosafety (ACGM, ACRE, ACNFP)

4.2.2 Integration of the results of the biosafety evaluation in a wider risk-benefit discussion on the introduction of new products.

4.3 In the first approach, an overarching body providing an umbrella structure to this current division of responsibility would help to ensure complementary decision-making, responsibility and accountability. The body would also help to set an overall strategy for the UK's approach to this new area of technology taking into account the European and global dimensions.

4.4 However, in Europe, these current biosafety mechanisms are being used by other groups to discuss other subjects not related to the safety aspect of individual product applications, such as broader ethical or socio-economic factors and consumer acceptance. It is unhelpful for companies who have received biosafety approval, to be stuck in the process by these wider considerations.

4.5 The second approach therefore would be for an overarching body to ensure that these other subjects are properly discussed and evaluated, demonstrating that Government decision-making is taking account of a number of different viewpoints. We envisage this forum to be the most appropriate place for consumer representation and discussion of consumer questions. We consider that safety evaluation is best left to the experts but a subsequent overall assessment of a product is needed to take into account the crucial question of consumer acceptability.

4.6 If this is deemed appropriate, we could envisage a two-stage system whereby biosafety approval on a product is separate from but followed by a wider evaluation of the total benefits versus risks (many perceived) of the product. This would give every interested party an opportunity to air wider considerations and values unrelated to the specific approved biosafety of a product. Companies would also need to be given the opportunity to present these benefits and to set perception of risk within a benefits context.

4.7 The creation of an overarching body, with the correct representation, could be a very positive step forward. If the advisory committee chairmen are to feed into this group, to be effective they must have sufficient resources provided by Government. Equally, individual chairs of the advisory committees need to be confident of Government support in the public domain.

5. *Capacity of the Government to be an "intelligent customer"*

5.1 We are confident that the Government has the capacity to be an "intelligent customer" for the advice it receives.

5.2 We perceive the Government to be rightly consulting all interested parties and not just the industry's, as portrayed. We are fully aware that our views are one of a large number that need to be taken into consideration.

5.3 We believe that Government decision-making does take proper consideration of the following factors:

— Scientific evidence regarding protecting of human health and environmental related issues

— Public concerns and consumer information and choice

— Benefits of the technology to sustainable agriculture, farmers and producers and potential benefits to improving health and economic benefits.

5.4 The OST's public consultation on biosciences and the Government's review of the framework for regulating biotechnology demonstrates its willingness to balance these different factors.

5.5 It is fundamental that the Government remains an "intelligent customer", making balanced decisions based upon a proper consideration of the science whilst responding to the wider questions raised.

In summary, it is vital that rigorous and comprehensive regulatory systems realise the priorities of safeguarding human health and protection of the environment, build public confidence in biotechnology and

its regulation and provide industry with a fair, transparent and efficient system for successful research and development.

15 March 1999

APPENDIX 11

Letter to the Committee Specialist from the British Association for the Advancement of Science

Thank you for your letter of 15 February about the Select Committee's case study on scientific advice to Government regarding genetically modified foods.

While being grateful for the opportunity to comment, the Association does not feel that it has anything of significance to add to the memorandum we submitted on the general system of scientific advice (copy enclosed)[4]. The one point we would like to stress is that the recent issues related to GMOs show the need for truly independent advice, if the public is to have confidence in the system. In some ways the bigger issue seems to be to how best to engender public trust/confidence in science and scientists and to enable them to take an informed/critical view of public utterances and media reports.

15 March 1999

APPENDIX 12

Memorandum submitted by the Medical Research Council

1. Introduction

MRC welcomes the opportunity to present evidence to the Inquiry's case study on GM foods which is being undertaken as part of the ongoing inquiry into the scientific advisory system. Many of the points we made in our submission to the general Inquiry are also relevant to this case study.

MRC funds a broad portfolio of research designed to elucidate the role of nutrition in human health and disease. Developments in molecular and cell biology and in genetics have provided new opportunities to develop understanding of the role of nutrition in health. Other funders—industry and MAFF—are better placed to fund studies designed to measure the toxicity and safety of particular GM foods. MRC's role is to develop the basic science in relation to human nutrition; develop relevant methodologies for assessing health impact at the population level (for example the randomised controlled trial—see below)[4]; and to provide independent, authoritative review of particular topics.

2. Adequacy and Quality of Current Scientific Advice

The Committee will hear from others about the status of scientific advice in non-health issues relevant to GM foods—it would be inappropriate for MRC to comment on those.

From soundings we have taken in the medical research community, there is reasonable consensus that the potential health effects of GM foods need to be analysed on a case-by-case basis. This sets a challenging agenda—both for science and for communication.

For the purposes of robust science, the most effective means of establishing the long-term effect of particular GM foods on human health will be the randomised controlled trial. The products and populations that would be needed for that approach are only now beginning to present. In the meantime, nutritionists, toxicologists, health scientists and toxicologists within the MRC community are starting to develop methodology for identifying susceptible groups, and the adverse parameters which could be measured in future trials and/or large scale epidemiological studies.

For communication purposes, the challenge of explaining that a small number of results in relation to one product do not necessarily extrapolate to all products has been demonstrated only too clearly over recent weeks. Once it becomes possible for MRC and others to set up some robust long-term trials, it will be vital to communicate negative results—ie those showing no adverse effect—as well as positive ones.

[4] Not printed.

3. Role and Framework of Advisory Committees

Most of the relevant issues, eg in relation to speed of response and co-ordination are covered in the next two sections.

4. Ability of Present System to Respond Rapidly to Scientific Developments

Science by its very nature will always move ahead of regulatory or ethical frameworks. Furthermore, controversy and uncertainty are part of science, and scientific findings will not always produce the clearcut answers that the public, the press and policy-makers might prefer. The "Public Understanding of Science" movement needs therefore to focus as much on developing understanding of the process of science as on its excitement and importance to national health and wealth. As we observed in earlier evidence, one of the main challenges is to work towards some agreed principles, and language, for assessing and communicating risk.

In summary, the number of layers in the system, and the unpredictability and pace of science, are less of a problem if the principles of risk assessment and risk communication are understood and observed responsibly by all parties—whether scientists, press, policy-makers or the public.

5. Value of an Over-Arching Body on GM Foods

MRC supports the setting up of a Foods Standards Agency and we would expect to be clearly positioned as one source of scientific expertise on which it would draw—both from our broad portfolio of nutrition research and from the specific expertise in the MRC's new national resource centre for human nutrition research in Cambridge which will conduct research on nutritional vulnerability and optimal nutritional status and provide an authoritative source of nutrition information.

More generally across the biosciences, we have yet to see a strong case for the centralisation which is sometimes mooted whereby a national body with a broad remit would debate advice from specialist committees before formulating advice to Government. The issues are highly complex and a strength of the present diverse system seems to us to be that ethicists, scientists and other specialists can work closely together towards solutions. If there is a move towards greater centralisation, it would be essential to ensure that channels of communication between scientists, ethicists and decision-makers were not lengthened. The tendency of large advisory bodies to develop their own culture and inertia would also need to be avoided.

In summary, the issues of public trust and the need for openness seem to us to be more fundamental than those of structure.

6. Government as "Intelligent Customer"

The move towards Concordat-style agreements between research councils and Government Departments, as part of the scientific advisory system, was based on the success of the relationship between MRC and the Health Departments in the previous Government White Paper on science (Ref).

Two aspects of that relationship as it has developed further in recent years are worthy to mention, as they may have broader applicability to the concept of the intelligent customer in other policy areas.

The first, is a move towards open and simultaneous presentaton of scientific evidence and of consequent policy. Publication in the Lancet last spring of a study on possible risks of MMR vaccine had caused considerable alarm in the press and to parents. In the spring of 1998, MRC convened, at the request of the Chief Medical Officer, a group of expert scientists to review the available data relating to a possible link between measles virus infection and inflammatory conditions of the bowel. The consensus—that the scientific evidence did not support a causal role for persisent measles virus infection in Crohn's disease and that there was no evidence to indicate any link between MMR vaccination and bowel disease or autism—was communicated to the CMO and to the public at a press conference hosted by MRC. The media had the opportunity to question both the scientific Chair of the MRC meeting, and DH policy-makers on the scientific evidence, and the implications for policy and for public health.

The second is the "horizon-scanning" element of the HDs/MRC interface. We have a planned programme aimed to keep the Health Departments abreast of current or planned scientific developments and the likely impact of these both on the health service and on public policy more generally.

12 March 1999

APPENDIX 13

Memorandum submitted by the Health Promotion Agency for Northern Ireland

INTRODUCTION

1.1 The Health Promotion Agency for Northern Ireland is constituted as a Special Health and Social Services Agency and reports to the Department of Health and Social Services for Northern Ireland.

1.2 The Health Promotion Agency provides leadership and strategic direction in health promotion in Northern Ireland. It is the major regional provider of health promotion services and it also plays a leading role in policy development and advice on health promotion issues.

1.3 As well as policy development and advice, the Agency's other main business areas include research, training, regional campaigns, public relations and the production of a wide range of publications.

1.4 The Agency is committed to working with many statutory, voluntary and private sector bodies and with national and international health promotion organisations.

1.5 In setting priorities among the specific health issues which it seeks to address, the Agency is guided by the *Regional Strategy for Health and Social Wellbeing in Northern Ireland* and the complementary Government strategy *Well into 2000*.

1.6 In this way it seeks to contribute to the integrated approach to improving health in Northern Ireland which is supported by all parts of the Health and Social Services in the province.

GENETICALLY MODIFIED FOOD

2.1.1 The Health Promotion Agency has not to date had experience of advising government on matters relating to the production and consumption of genetically modified foods or on the potential impact on human health or the environment.

2.1.2 The Health Promotion Agency wishes to thank the Science and Technology Committee for the opportunity to make a submission to the Genetically Modified Food Inquiry.

2.2 *Long-term implications of genetically modified foods*

2.2.1 The technology that allows for the production of genetically modified foods is a relatively recent development. The Agency believes that the potential long-term effects on human health and the environment should be examined and until these are known, the range of genetically modified foods should be restricted.

2.3 *Labelling of genetically modified foods*

2.3.1 The Agency believes that it is essential that consumers have the opportunity to make informed choices about the food they buy. This highlights the importance of clear and unambiguous labelling of all foods or food products which contain genetically modified constituents.

2.3.2 The Agency understands that the current practices regarding genetically modified maize and soya make it impossible to identify soya and maize that are genetically modified from those that are not.

2.3.3 The Agency believes that this situation should be examined and mechanisms put in place to allow adequate labelling of all foodstuffs derived from genetically modified crops.

2.4 *Formation of an advisory body on genetically modified foods*

2.4.1 The Agency would welcome the establishment of an overarching body, which would be charged with providing advice and overseeing all genetically modified food issues. This body should take account of consumer interests and environmental aspects of genetically modified food production and should be independent of industry interests.

15 March 1999

APPENDIX 14

Memorandum submitted by the Biotechnology and Biological Sciences Research Council (BBSRC)

INTRODUCTION

1. The Biotechnology and Biological Sciences Research Council (BBSRC) was established by Royal Charter in April 1994. It is a non-Departmental public body principally funded by the Department of Trade and Industry via the Office of Science and Technology and through the Science Budget. BBSRC sponsors research in both its own institutes and in universities. BBSRC institutes receive a proportion of their funding

from the Ministry of Agriculture, Fisheries and Food (MAFF) by means of research commissioned on a consumer/contractor basis, and research support from other Government Departments, the EU and industry.

2. The Council's mission is:

— To promote and support high quality basic, strategic and applied research and related post-graduate training relating to the understanding and exploitation of biological systems;

— To advance knowledge and provide trained scientists and engineers which meet the needs of users and beneficiaries (including the agriculture, bioprocessing, chemical, food, healthcare, pharmaceutical and other biotechnology-related industries) thereby contributing to the economic competitiveness of the UK and the quality of life;

— To provide advice, disseminate knowledge and promote public understanding in the field of biotechnology and the biological sciences.

3. BBSRC sponsors several institutes that can provide expert advice to Government on issues related to the production, safety and environmental impact of genetically modifed (GM) crops and food products derived from them. Specific areas of expertise include:

— the stability and predictability of genes that have been transferred into crops by genetic modification: do the genes do what was intended, are there side effects in the crop that were not expected, do the effects continue in subsequent generations of the crop? (Institute of Arable Crops Research (IACR), John Innes Centre (JIC), Institute of Grassland and Environmental Research (IGER) and the MAFF sponsored Horticulture Research International (HRI));

— the likelihood and implications of gene transfer from GM crops to other crops and to wild species. Genes can be transferred between related species eg by pollen transfer. The ease by which this happens is different for different species. (IACR, JIC, IGER);

— secondary effects: how will the new properties of the changed crop affect other species, and in particular, what will be the effect on biodiversity? Note, however, that there have been major recent changes to biodiversity caused by changes in farming practice that have nothing to do with GM crops, and great care must be taken not to attribute these effects to GM crops which have other causes (IACR);

— gene transfer between micro-organisms, including those in the gut, and issues for food safety: this has been an issue particularly with respect to the introduction of antibiotic-resistance markers, a practice which has been phased out (Institute of Food Research (IFR));

— the fate of DNA in the diet: does DNA transfer directly from the gut into human cells and replicate; this is not known to occur at all, and is not specifically an issue for GM food, but has been raised as an issue (IFR);

— consumer attitudes to biotechnology; food choice (IFR).

Although there are currently no proposals to develop GM livestock for food production, the Roslin Institute can provide advice on issues relating to the production of GM animals.

4. BBSRC funds research relevant to the Committee's inquiry at several universities, notably at the University of Nottingham (Professor Don Grierson who developed the GM tomato used in GM tomato purée on sale world-wide) and Royal Holloway and Bedford College, London (Dr Peter Bramley).

5. BBSRC employees sit as members on several of the regulatory committees (as at August 1998):

ACGM: Professor Mike Gale (JIC).

ACGM Technical Sub-committee: Dr Penny Hirsh (IACR).

ACRE: Dr Phil Dale (JIC) and Dr Ingrid Williams (IACR).

ACNFP: Dr Mike Gasson, Deputy Chairman (IFR) and Dr Phil Dale (JIC).

The Adequacy and Quality of Scientific Advice at Present

6. It is widely accepted that public confidence in government's ability to obtain and use authoritative scientific advice is at a low ebb as a result of the BSE crisis. The BSE crisis cast doubt in the public's mind on the credibility of scientific judgement because the advice given to government was seen to change and advisers were seen to take strongly opposing views. The more recent public concerns about GM food have been given an extra twist by the suggestion that scientists working in the area of GM with industrial funding will inevitably offer biased advice to government, and that government itself cannot be trusted to deal impartially with scientific advice because of individual and/or collective commitment to policies for economic/industrial growth.

7. Against the background, there are clearly some weaknesses in the current structures for obtaining advice:

— lack of linkage between policy development and scientific research strategy: The advisory bodies are essentially reactive to applications, and do not have an independent role (and budget) to pursue

their own research agenda so as to better inform their decisions. The FSA as proposed ought not to suffer from this weakness.

— lack of transparency: Advice to government through the Whitehall machinery is perceived as suspect because it passes through the "sifting" process of the administrative structures. An ability to place authoritative research directly into the public domain would be desirable.

— conflicts of interests: The search for advisors who are totally "independent" is likely to be illusory. Very few scientists with a knowledge of the subject are likely to approach the subject without a clear framework of analysis, and the non-scientists, including those from "green" organisations have their own interests too. The government should therefore seek to have all external links clearly declared and to ensure that the numbers of members of advisory committees with a direct recurring interest in this technology is small or zero; in particular, it is essential that the Chairs are entirely competent to handle these difficult judgements and are above reproach.

8. It is a feature of biotechnology that technological advances derive from, and are very closely linked to, discoveries from the fundamental science base. Independent (non-industry) experts tend to be academic researchers working on fundamental issues that are not directly linked to specific applications. The result may be a hiatus between the types of question that can be answered from the science base, and those of a more practical level that are being raised by the public. In conventional agriculture, for example, one might not seek advice about crop safety from an academic geneticist, but from a plant breeder or an agronomist; with GM crops, it may be that academic advice needs to be supplemented with that from corresponding practitioners.

The Role and Framework of Advisory Committees

9. Issues relating to GM foods primarily fall within the remits of the Advisory Committee on Release into the Environment (ACRE) and the Advisory Committee on Novel Foods and Processes (ACNFP). There is also a role for the Food Advisory Committee (FAC), the proposed Advisory Committee on Animal Feedingstuffs (ACAF) and the Pesticides Directorate. ACNFP provides advice on all applications to market GM foods. It is not yet clear how the Food Standards Agency will fit into this framework. ACRE and FAC are statutory bodies, whilst ACNFP (and the proposed ACAF) is a non-statutory body.

10. The advice from the above committees is provided to different Ministries, though there is some overlap. The areas of responsibility of the different committees is reasonably clear; nevertheless, effective lines of communication are needed between these committees if the advice is to be consistent and all aspects of producing GM foods are taken into account.

The Ability of the Current System to Respond to Rapid Scientific Developments

11. ACRE and ACNFP should be in a position to respond to rapid scientific developments which fall within their remits, though the statutory nature of ACRE may inhibit it from considering issues outside its defined remit.

12. An important factor in responding to scientific developments is the membership of the Committees. Members need to be sufficiently aware of progress to highlight any issues which are likely to impact on the production of GM foods, but also, there needs to be flexibility to revise the membership so that it has the expertise required to address fully the issues raised by new developments. The involvement of active scientists with established reputations who are at the forefront of their fields of expertise is essential, and facilitates the ability of a committee to respond to rapid scientific developments.

13. However, the lack of an overview means that novel developments could be missed if they fall outside the remits of the individual committees. There should be regular reviews of the terms of reference of the committees to ensure that they are in line with recent developments.

To What Extent there is Value in the Proposal for an Overarching Body to Advise On and Oversee All Genetically Modified Food Issues

14. The area would benefit from a single body looking at all these issues, in addition to the existing Committees, through receiving input from them. In our response to the "Review of the Framework for Overseeing Developments in Biotechnology" (Annex)[5] we suggested that a Biotechnology Commission would be an option, though this would have a wider remit than just food. We see the production of GM foods as falling within its remit.

15. An overarching body could address issues which it is perceived the existing committees fail to cover including risk/benefit analysis and ethical issues.

[5] Not printed.

THE CAPACITY OF GOVERNMENT TO BE AN "INTELLIGENT CUSTOMER" FOR THE ADVICE IT RECEIVES

16. As stated above, advice on GM foods is provided to, and impacts upon, a number of Government Departments. The capacity of the Government to act as an intelligent customer will be affected by how well the advice is co-ordinated. However, the establishment of the Ministerial Group to oversee developments in genetic modification is a positive step as are the reviews which have been put in place in response to public concerns.

15 March 1999

APPENDIX 15

Memorandum submitted by Consumers in Europe Group (CEG)

THE CONSUMERS IN EUROPE GROUP (CEG) IS AN INDEPENDENT UK UMBRELLA BODY FOR 34 UK ORGANISATIONS WITH AN INTEREST IN THE EFFECTS OF EUROPEAN UNION POLICIES AND PROPOSALS ON UK CONSUMERS

1. Although the issues that the inquiry covers relate mainly to domestic UK matters, the UK system fits into a broader framework of European regulation of biotechnology. CEG has been interested for many years in genetically modified (GM) foods as a policy issue of key concern to consumers. Our comments below are focused mainly on the food aspects of biotechnology. We have been less involved in the environmental implications of GMO (through lack of resources).

2. As a general comment, CEG is not against genetic modification in itself, provided it is tightly controlled. We recognise that this new technology could potentially offer benefits to consumers. However, consumer confidence in genetic modification is facing a crucial time as the first GM commodity crops are used as sources for a wide range of food ingredients. CEG appreciates that many consumers are concerned about genetic modification of crops and the foods produced from them.

3. The approval process for GM crops and GM foods is split between many different scientific committees, both at UK and EU level. Each committee has a strict remit and considers each approval on a case-by-case basis. As stated in the recent Royal Society report, "there is no means for looking at GM technology as a whole". In particular, there is no committee to look at the wide-ranging impact and ethical issues surrounding the use of genetically modified crops to produce food and the effects that they have on the food chain from farm to consumer. This gap affects issues such as segregation of GM and non-GM foods and also how labelling schemes could be introduced and validated through the supply chain.

4. CEG recommends that the European Commission and the UK set up overarching committees to consider the wide-ranging impact of genetic modification on consumers and the environment.

5. The UK advisory system should have good working relations with equivalent parts of the European Commission's scientific advisory system. Representatives from EU and UK scientific committees could attend their relevant UK or national counterparts to explain how their committees operate (particularly after the recent changes at EU level) and to present the outcome of key evaluations. Good communication between the Agency and Commission should enable both sides to learn and benefit from the methods adopted by the other on, for instance, consumer involvement.

6. A small amount of overlap in responsibilities between advisory committees is preferable to having gaps. However, the overlap should not be so great that having two or more committees each looking at the same issue wastes resources. There should be more co-ordination and liaison between committee secretariats and members. This is especially important between committees that are responsible to different government departments.

7. The current UK advisory system is very complicated and appears to have little or no under-lying reasoning to it. The current and predicted future workloads of the committees on GM issues should be reviewed to see if committee remits could be altered to reduce the number of committees dealing with GM issues. If necessary, the areas of expertise on committees may need to be changed.

8. The openness and transparency of the system is of great importance for improving consumer confidence. Some improvements have already been made and these should be encouraged and developed. In line with EU scientific committees, the agenda, minutes and opinions of UK advisory committees should be placed promptly on the Internet, and made available in hardcopy. Similar details should be made available of any sub-group meetings of the committees. The guidelines and principles that are used by the committees in the decision-making process should be made publicly available. A consumer-friendly explanation of the system should be published. Merely putting documents on the Internet and publishing leaflets is not sufficient. The system should have a duty pro-actively to inform consumers about its work in a way that reaches a large proportion of consumers and in a way that they can understand and trust.

9. There are few, if any, formal opportunities for consumers to make their views known to advisory committees and, more importantly, few opportunities to influence policy-making. CEG has had little participation in the advisory system other than responding to consultations on legislative proposals and nominating consumer representatives to the ACNFP.

10. Consumer representation on the advisory committees dealing with biotechnology is variable in number (none, one or two) and in type (consumer representative and/or lay person). It should be increased to two consumer representatives per committee across the system. This number offers a measure of support to non-experts, who might otherwise feel intimidated by a meeting of academic scientists, and could be managed so that their terms overlap to provide continuity of representation. Consumer representatives must be given necessary resources, in terms of both training and finances. Training (in technical subject matters and presentation skills), advice and resources are needed by consumer representatives in order for them to play an effective role on committees.

11. An environmental stakeholder forum to shadow the Advisory Committee on Releases of Genetically Modified Organisms into the Environment (ACRE) is an interesting idea. Interested parties could discuss general issues affecting the work of ACRE and could also review the advice given by ACRE. Consumers should be represented on such a forum. There seems to be little reason why the idea should not be extended to the food area to a food stakeholder forum shadowing the Advisory Committee on Novel Foods and Processes (ACNFP) and the Food Advisory Committee (FAC), and which could include consumers, food manufacturers, retailers etc.

12. In addition to the above systems, there need to be ways in which ordinary consumers (as well as consumer groups) can discuss GM policy issues. One way might be to use national or local consensus conferences. They could be organised by the proposed Food Agency. It is important that the outcome of the discussions would feed back to government in such a way, and at an appropriate time, to influence policy decisions. Otherwise, they will just be seen as "talking shops".

13. This technology is still at an early stage of development, at least where food is concerned. CEG wants GM food to be thoroughly evaluated for safety and to be tightly controlled. A precautionary approach should be applied where there is uncertainty over risks to human health. The current regulatory requirements should not be relaxed until more is known about genetic modification of food and its long-term consequences.

14. The general unease felt by many consumers towards genetic modification reflects to some extent their lack of confidence in the present regulatory system. For the public to have confidence in the system, the public should first be aware that there is a system in place, should appreciate how the system works and should accept the decisions that the system produces. CEG doubts whether the public knows enough about the system at present to be able to judge it fully.

15. The independence and credibility of MAFF committees may improve when they are transferred to the Food Agency. These committees (such as the FAC, ACNFP, and the Advisory Committee on Animal Feed) will need to review their work procedures in advance of their move to the Agency.

March 1999

APPENDIX 16

Memorandum submitted by the Farmers' Union of Wales

Introduction

The FUW welcomes the inquiry being conducted by the Science and Technology Committee of the House of Commons into the Scientific Advisory System and Genetically Modified Organisms (GMOs) and submits the following brief memorandum for the Committee's consideration.

The FUW

The FUW is an independent organisation representing the interests of farmer members in Wales. Its membership comprises largely of traditional family farmers.

The Union has a close liaison with its grass-root members through its County Branch structure. FUW policies are determined, in response to views submitted to the appropriate Head Office Committee from its 12 County Branches.

80 per cent of Wales is designated less favoured by the EU. This is reflected in the fact that 87 per cent of the gross output of Wales emanates from the milk, beef and sheep sectors.

FUW Approach to GMOs

The FUW has consistently advocated that food should be regarded as pure and unadulterated and this, the Union believes, will become increasingly important in the context of a strategy to develop the Welsh food industry. The FUW is cognisant of the need to respect consumer attitudes, since ultimately, demand for primary production and processed foods depends on the consumer's willingness to purchase such. Despite surveys indicating consumer opposition to the inclusion of GMOs in foodstuffs, their inclusion is still permitted. The FUW has, in recent years—and well in advance of the recent furore—expressed concern that

the development of GMOs and their inclusion in foodstuffs was being permitted without addressing legitimate concerns by both producers and consumers as to the safety of such bio-technological manipulation.

The FUW has, in recent years, made representations to Government departments and also to the Advisory Committee on Novel Food processes expressing its concern at the development of GMOs.

The FUW is unhappy that at present labelling requirements are not such as to permit the consumer to exercise a choice as to whether or not to purchase food with GMOs since those that are chemically identical to the conventional product do not have to be labelled.

Farmers, as primary food producers, are particularly vulnerable since they may unwittingly be purchasing imported feed for livestock to which has been added genetically modified maize or soya and which, because it is identical to the conventional product, does not have to be segregated or labelled as such. Given that there is a demand by the consuming public for primary produce such as milk, beef, lamb, pig and poultry meat that has not been produced using genetically modified feed, this, under current controls and labelling practices, would be difficult to guarantee. This poses particular difficulty for farmers given the "due diligence" requirements now imposed on the industry.

Unambiguous labelling of all livestock feed and the human foods produced therefrom and thus containing GMOs is an absolute minimum requirement.

The Adequacy and Quality of Scientific Advice

The Union's understanding is that modified crops have only been available since 1983 and the FUW fears that GM crops are being introduced on too large a scale—there is a need to assure genetic diversity—too quickly, with inadequate consideration of long-term implications and with insufficient oversight.

The FUW believes that an EU wide moratorium should be imposed on the commercial sowing of GM crop products which are scheduled to commence next year. This would provide more time to analyse and assess research that has been undertaken to date and to undertake further independent research to evaluate the possible long term dangers that may be posed by GM crops.

The Role and Framework of Advisory Committees

Despite the fact that GM crops have been available since 1983 relatively little information has been disseminated to the industry. The FUW is of the view that the results of experiments and trials should be made more widely available to the industry in a form that is meaningful and "digestible" to lay persons.

Overarching Body to Advise on and Oversee all Genetically Modified Food Issues

There has been criticism that in the United States, where there is a tendency to be less concerned for food safety issues, that the regulatory framework is piecemeal relying on the Department of Agriculture, the Food and Drug Administration and the Environmental Protection Agency. The FUW believes that there is a strong case for a more integrated and co-ordinated approach that provides impartial advice to both primary producers and consumers. This may, in the UK context, be a role for the new Food Standards Agency.

In conclusion the FUW would reiterate that it is unhappy with the speed with which genetically modified foods are being progressed. It is anxious that labelling requirements are not sufficiently rigorous for discerning users of livestock feed or purchases of food. The Union believes that more independent research is required pending the commercial growing of modified crops and that a more holistic strategy should be adopted in terms of provision of impartial guidance and advice on GMOs to both primary producers and consumers.

15 March 1999

APPENDIX 17

Memorandum submitted by the Royal Commission on Environmental Pollution

1. The Royal Commission on Environmental Pollution's Thirteenth Report, published in 1989, considered the release of genetically modified organisms (GMOs) into the environment and its recommendations shaped the legislation which now regulates GMO releases. In the last decade there have been changes in the understanding of environmental problems which have led the Commission to look at the issues involved in a broader and more fundamental way. In responding last month to a government consultation paper on Future Oversight of Developments in Biotechnology, the Commission sought to apply the general conclusions about environmental policies reached last year in its Twenty-first Report, *Setting Environmental Standards*. The Commission's response is in the public domain; a copy is attached for ease of reference.[6] This memorandum is intended to bring the salient points of the response to the Committee's attention.

[6] Not printed.

2. The Commission's Twenty-first Report pointed to an erosion of trust in regulation, and a questioning of the traditional paradigm of government regulation informed by small groups of experts as the appropriate way of making policy in conditions of uncertainty. This trend has affected environmental regulation generally but there are some specific weaknesses in the system for regulating GMOs. In particular, the reductionist method of risk assessment used has appeared to close off from scrutiny the possibility of cumulative and indirect effects, and ethical and other wider concerns about the release of GMOs.

3. This gap in the regulatory structure is symptomatic of a deeper failure, the lack of a satisfactory and systematic means of taking public values into account. The Royal Commission understands values to be beliefs about what is important in life, and thus about the ends or objectives which should shape public policies. Once formed, such beliefs may be durable. It is also characteristic of them that they may be formed and modified as a result of information and reflection. Processes of debate and discussion may facilitate the emergence of values. They may also help to resolve situations in which different values are competing with each other, thereby helping to create or identify policy choices which will command wide support.

4. One addition to the regulatory framework which has been proposed is an environmental stakeholder forum. The "stakeholder forum" model places the emphasis on negotiation and compromise instead of teasing out the implications of issues and thereby enabling mutual learning to take place, views to evolve, and a more robust conclusion to be reached. It is the values of people in their capacity as citizens which need to be included in the debate. The interests of stakeholders, though important, do not cover the whole spectrum of moral and social concern.

5. Applying to GMOs the analysis of its Twenty-first Report, the Royal Commission's response to the government consultation paper envisaged that a body should be established in parallel with existing sources of technical and scientific advice, in order to feed into key stages of the regulatory procedure. Its purposes should include using innovative approaches to articulate people's values. To avoid the risk of dominance by centralised, metropolitan views it would be desirable for such a body to use, as its agents, a range of organisations such as local authorities, universities, libraries and cultural organisations across the country. It would be important to be independent, not only of the biotechnology industry, but also of existing regulators.

6. The output from this new body must be utilised in the decision-making process to inform the framing of questions about proposals for releases and the formulation of policy aims. This implies that it should have a formal reporting line to the civil servants and Ministers who set the regulatory framework and decide on specific applications.

7. There is no need for the advisory bodies themselves (scientific, ethical etc) to have an hierarchical structure, as each has its own function. There should nevertheless be contact and co-ordination between all the component bodies in the regulatory system because they will be reliant on each other for information and data. Issues considered by, for example, a scientific advisory body are informed by people's values, just as those values can be adequately developed only with the help of reliable information from scientists. The information available to experts and non-experts alike should be continually improved to raise the standard of the debate. The debate itself should be structured so that the underlying assumptions and values are made explicit.

8. In order to achieve transparency, each body's output should be in the public domain, and should be considered by the decision-makers together with the outputs from the other bodies involved. This will enable policies to be informed by people's values as well as by the best scientific, technological, economic and other analysis. A further means of achieving greater transparency would be to place an obligation on decision-makers to issue reasoned decisions, as is the case for example when land use planning appeals are decided. The scale of the justification provided for a decision should be commensurate with the weight of the issues in an individual case.

9. The Royal Commission believes that the proper articulation of people's values is a necessary preliminary to informed and robust debate. It is not a panacea but giving priority to that task could help considerably to improve the quality of the debate on GMOs and ensure that the policy issues which arise are settled in ways which command the widest assent.

15 March 1999

APPENDIX 18

Memorandum by the Scottish Office

INTRODUCTION

1. The Secretary of State for Scotland together with the Minister for Agriculture, Fisheries and Food, the Secretary of State for Health and the Secretary of State for Wales, has joint legislative responsibility for most issues relating to genetically modified food. The Secretary of State also has responsibilities for public health in Scotland and in relation to food safety, policy is formulated and implemented in close liaison with MAFF and DH.

2. Policy areas with an interest in genetically modified food and crops are spread across a number of Scottish Office Departments:

— Agriculture, Environment and Fisheries Department (AEFD)—food safety, biodiversity issues, research, crops and seeds, scientific advice.

— Education and Industry Department (EID)—developing the GMO industry.

— Department of Health (DoH)—impact of GM foods on human health, also wider biotechnology implications for health care such as xenotransplantation.

(This Memorandum should be read with that provided by MAFF/DH which covers the UK position.)

THE SCOTTISH OFFICE: SUMMARY OF ARRANGEMENTS ON GM ISSUES

4. The Scottish Office relies principally on the Advisory Committee on Novel Foods and Processes (ACNFP) for scientific advice on genetically modified food and on the Advisory Committee on Releases to the Environment (ACRE) on issues relating to releases to the environment eg trials of genetically modified crops. As specified in their respective terms of reference both Committees report to Scottish as well as other UK Ministers. The Scottish Office also has assessors on both Committees. All members are appointed on behalf of UK Ministers and include a number of scientists from Scottish research institutes and universities.

5. The Scottish Office does not at present have other sources of scientific advice outwith the ACNFP and ACRE arrangements. However, provision is being made for the Scottish Agricultural Science Agency (SASA) to provide additional scientific input on GM crop issues. The policy is determined largely on a UK basis in close collaboration with Whitehall Departments. The Scottish Office examines in particular any Scottish aspects in relation to policy formulation; all the GM food issues considered thus far have been UK wide with no specifically Scottish aspects.

6. Post devolution legislative responsibility for GM food will be devolved. However, the above arrangements for access to scientific advice primarily through ACNFP and ACRE, with additional scientific input from SASA, can continue with no new separate sources of advice needing to be set up. These arrangements will, subject to the views of the Scottish Parliament, be formalised under the new Food Standards Agency which, it is proposed, will be a UK body, but with a strong Scottish arm advising Scottish Ministers post-devolution.

7. The Scottish Office also funds research into genetically modified crops. This research is of a strategic and underpinning nature and is designed not to inform policy on genetic modification projects so much as to advance the underlying science and understanding of genetic modification and its effects.

MAIN ISSUES

Departmental Decisions to seek Scientific Advice on GM Food and Crops

8. The Department discusses these matters jointly with Whitehall Departments. If advice on specific matters is required the authoritative view would be obtained from ACNFP and ACRE.

Sources of Scientific Advice to Inform Decision and Policy-making Regarding GM Food and Crops

9. The ACNFP and ACRE are the primary sources of scientific advice, as noted in paragraphs 4 to 6 above. Within the Department the Chief Medical Officer for Scotland and professional staff in his area feed into policy development, as well as expertise being available from SASA and other crop-related scientific bodies.

How is Conflicting Scientific Advice Balanced?

10. Essentially a matter for the ACNFP and/or ACRE. Policy is developed in close liaison with MAFF, DH and DETR.

Other Factors Taken into Account When Formulating Policy

11. Policy is formulated in close liaison with MAFF, DH and DETR given that almost all issues have UK-wide applications. Policy relies very heavily on the scientific advice. Issues of practicality and enforcement are also carefully considered before policy decisions are taken. The scientific advice is the driver; other factors are taken into account essentially to ensure effective implementation.

Mechanisms to Ensure Consistency with Other Departments

12. There is close liaison at all levels between Scottish Office officials and those of other Departments with GMO interests. A Scottish Minister is currently part of the Ministerial Group on Biotechnology and Genetic Modification, and there is Scottish Office representation at the related officials' meetings which take forward the agreed views and requirements of the Group.

13. The Scottish Office also takes active part in the Interdepartmental Group on Genetic Modification Technology (IGGMOT) which is serviced by the Office of Science and Technology (OST). The Group provides a neutral forum for debate of GM policy at official level across Government. Its remit is to co-ordinate and develop cross-departmental policy on GM technology and to co-ordinate presentation of the policy in the EC and international fora. Membership includes Government departments and research councils, ensuring an ongoing link between policy and developing science. These arrangements will continue post devolution with IGGMOT likely to be the main means for co-ordination of GM policy post devolution.

Assessment of Merits of Scientific Advice

14. The mechanisms here are close liaison with MAFF, DH and DETR and access to the same scientific advice through the ACNFP and ACRE.

Scottish Office Involvement with Research Undertaken by Dr Pusztai in the Rowett Research Institute

15. In 1995 The Scottish Office funded a three-year collaborative research project involving the Rowett Research Institute, the Scottish Crop Research Institute and the University of Durham, entitled "Genetic Engineering of Crop Plants for Resistance to Insects and Nematode Pests; Effects of Transgene Expression on Animal Nutrition and the Environment". The Rowett Research Institute's component of this was to conduct a series of rat feeding trials to test the nutritional effects of feeding the rats different diets of potatoes, and particularly the effects of introducing lectin proteins into the potato samples: lectins are naturally-occurring proteins which are toxic to certain species, and the intention was to identify lectins which would confer on the potatoes a resistance to pests but which would have minimal, if any, nutritional effect on animals eating the potatoes, or more generally on the environment.

16. Early in 1998, Dr Pusztai, the project leader at the Rowett and the co-ordinator of the collaborative project, was reporting that adverse effects on the rats were being detected. The project was at that time not yet completed and was not due to finish until the autumn of 1998. Under standard procedures, however, researchers involved in such projects are required to discuss their results with their collaborators, to agree with their collaborators the conclusions arising from the project, and to seek the agreement of their collaborators and funders to preparing the results for detailed peer review and subsequently for publication. In this case Dr Pusztai made statements in the media in August 1998 in advance of this and Professor Philip James, Director of the Rowett Research Institute, decided to suspend Dr Pusztai from further work on the project and appointed an Audit Committee to review the evidence on which Dr Pusztai's conclusions were based. Dr Pusztai continued, however, to be employed by the Rowett until his annual contract expired in December 1998.

17. The handling of these events was a matter for Professor James as Director of the Institute and The Scottish Office were not involved in the decisions he took. The Scottish Office's position remains that Dr Pusztai's data, and any associated data, should be subject to independent peer review and, as appropriate, prepared for publication in the normal manner. The Scottish Office welcomes the agreement of the Royal Societies to conduct such a review.

16 March 1999

APPENDIX 19

Memorandum submitted by the Food and Drink Federation

1. INTRODUCTION

1.1 The Food and Drink Federation (FDF) is the leading representative of the UK food and drink manufacturing industry, the largest manufacturing sector in the UK. It accounts for 22 per cent of total purchases by consumers and buys and uses 70 per cent of UK agricultural produce. The industry employs approximately 500,000 people and its gross annual output amounts to more than £50 billion.

1.2 The primary role of the food and drink industry is to provide a wide choice of safe, wholesome food at affordable prices all year round. FDF represents members at various stages of the food chain, from the suppliers of ingredients used in very small quantities to the manufacturers of consumer end-products, but not primary production or retail.

1.3 Biotechnology is an important strategic science of potentially enormous benefit to the food and drink manufacturing industry. FDF believes that the technology can offer enormous benefits in the food supply chain, in primary production, in food manufacture and to the final consumer, as well as to the environment.

2. The Adequacy and Quality of Scientific Advice at Present

2.1 FDF commented last year on the Scientific Advisory System in general, in response to the Committee's main enquiry (memorandum entitled "House of Commons Science and Technology Committee Inquiry into the Scientific Advisory System" dated 5 August 1998). FDF also responded to the Government Review of the Framework for Overseeing Developments in Biotechnology in January this year, in which we commented on the Advisory Committee structure. Many of the points made are relevant to this enquiry and are therefore repeated here.

2.2 It is difficult to comment on the adequacy and quality of scientific advice without the ability to conduct an independent audit of a particular committee's work. Whilst we endeavour to "shadow" the work of the ACNFP through one of our own expert committees, we do not have access to the papers they are reviewing and would not necessarily have access to all the appropriate expertise to review them. The publication of agendas and post-meeting reports gives little insight into the actual studies under review, only the subjects, though the lengh of time taken to review a particular submission and the number of times it reappears on the agenda with indications that further information has been requested, suggests that the review is thorough.

2.3 Seeking to place checks on the advisory committees by duplicating their work would clearly be impracticable. It is therefore of paramount importance that the committees and their members command the confidence of all concerned, from the Government itself, through the scientific community to the general public. There are parallels in other areas of consumer safety, eg air travel, where the expertise of the professionals operating the aeroplanes and the authorities which check and control their performance, is not questioned because there is general trust in the system and most members of the public would not claim to be knowledgeable about the intricacies of airline maintenance. It is regrettable that, where food safety is concerned, and particularly where genetic modification is involved, a remarkable number of people appear to believe that they, or individual scientists who have expressed a view with which they agree, know more about it than the Government-appointed experts in the field, who we would assume to be the best available in their respective fields of scientific expertise. The BSE crisis seriously dented public confidence in the safety of the food supply and this has had enormous impact on the introduction of GM food ingredients, particularly soya. The experience of BSE is frequently cited as a reason for not using GM ingredients and for not trusting scientific opinion. This is a difficult situation to redress as no human activity is entirely risk-free and it is impossible to prove a negative. Greater openness and better public communication may assist in reassuring the public that careful controls are in place.

2.4 FDF welcomes and supports the move towards greater transparency in the work of the Advisory Committees and the introduction of Nolan recommendations in appointing members of the committees. FDF also welcomes the introduction of lay members to the Committees to address the perception of greater transparency and direct consumer involvement. However, it is important to retain the primary role of the Advisory Committees as the provision of independent expert scientific advice to ministers. The importance of individual members being appointed for their individual expertise cannot be over-emphasised. This expertise must be in those areas of science encompassed by the Committee's remit. The "lay member" should, therefore, have an appropriate scientific background to allow him or her to make an active contribution to the debate from a position of authority, not simply act as an observer to the process. The latter role might well serve to reassure some audiences that "consumer" views were being taken into account but would not necessarily contribute positively to the decision-making process and could weaken the overall authority of the Committee. Indeed, the need is more for an individual who can audit the process of scientific evaluation and assessment to ensure its rigour and objectiveness.

2.5 It is important to achieve properly balanced representation on principal committees, such as ACRE and ACNFP. Much expertise resides within the food industry itself. There is no reason why this should not be exploited within the Advisory Committee structure. Such an expert would clearly be identified, as is the case in the FAC, and while providing expertise it would also help to broaden industry's understanding of the concerns of other parties. The ACNFP does not have a single scientific expert currently active in the food industry, or indeed any industrial expertise. This would seem of itself undesirable in inhibiting the Committee's access to direct expertise of food processing and technology.

2.6 There is a growing perception that any individual with direct or indirect commercial interests, such as industrial employment or ownership of shares in relevant companies, should automatically be barred from membership of the Advisory Committees because of conflicts of interests and the risk of actual or perceived bias. Moreover, with research funding increasingly being derived from industry, there are few relevant academic institutions and departments not in receipt of industry funding, which arguably could exclude many well-qualified academics. FDF believes that the mechanisms for declaration of interests and ensuring the confidentiality of commercially sensitive data are robust and any suggestions that industrial employment or connections should automatically disqualify otherwise very appropriate candidates should be firmly rejected. The absence of industrial input into the decision-making process can lead to decisions being taken without

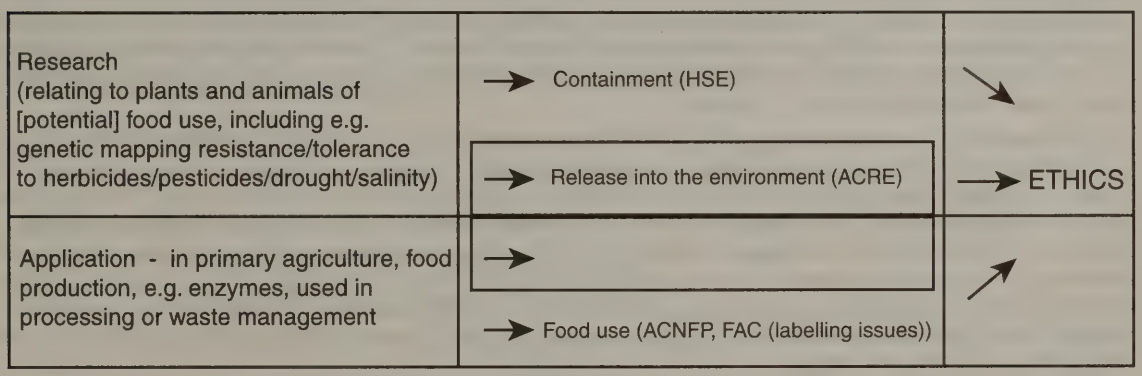
adequate knowledge of the consequences to the food processing chain or the marketplace. Whilst such matters should not influence scientific decisions as to, for example, the safety of a GM crop or product, it may influence advice as to how it is introduced and placed on the market.

3. The Role and Framework of Advisory Committees

3.1 In view of the position of FDF as the principal representative body of UK food manufacture, it is the ACNFP with which we most closely associate our area of business in that it has responsibility for assessing all novel foods and novel food ingredients. We do, however, also monitor the work of the Advisory Committee on Releases to the Environment (ACRE), to the extent that this is often the first stage of entry onto the market of a potential food raw material. We are also aware of the role of the Health and Safety Executive (HSE) in respect of containment and deliberate release, though this is not an area in which we have direct expertise. ACRE's decisions and reports are an excellent source of information for our sector of the industry and we understand its work to be generally respected.

3.2 The increasing importance of the Advisory Committees places an additional burden on the Chairmen and Secretariat, whose competence and ability will be constantly under scrutiny and in the public spotlight. The Chairmen need to be strong spokesmen and capable of dealing with the media and a range of interest groups, including single-issue activists. Given that they are generally full-time academics, it is important that they are not only willing, but enabled to devote sufficient time to the task and that they are appropriately supported in their public duties by a competent and adequately resourced Secretariat. They are the public face of the Advisory Committee infrastructure. They, and their committees, should also enjoy the explicit support of the Government. Undue criticism of their independence or individual decisions is unwarranted, serves to undermine public confidence and should be robustly rejected.

The following table summarises the areas in which modern biotechnology and genetic modification impact on the food and drink industry, both directly and indirectly, and the issues and advisory bodies which relate to them:



The Advisory Committee system fulfils two important roles:

- Independent review and assessment by independent and objective experts of the science or issue in question.
- Public confidence in decisions perceived to have been taken on the basis of independent expertise not subject to commercial or political pressure.

The Advisory Committee structure in the UK has proven to be robust and is well-respected. This structure should be supported and strengthened where necessary.

4. The Ability of the Current System to Respond to Rapid Scientific Developments

4.1 FDF has frequently expressed concern that the regulatory system lags behind the development of the technology. The regulatory system is, to a great extent, dependent on scientific advice. It is a matter of concern that the technology may not be allowed to develop because of regulatory constraints and lengthy decision-making process. The UK Advisory Committee system cannot correct or improve on a regulatory system developed at EU level, but nor should it act as an additional hurdle placing further burdens on an already highly regulated industry. The Advisory Committees therefore need to be able to review evidence rapidly, and their members need to be at the cutting edge of the technology.

5. To What Extent is there Value in the Proposal for an Overarching Body to Advise On and Oversee All Genetically Modified Food Issues?

5.1 Biotechnology covers a broad spectrum of interests including, and probably most significantly, the medical and pharmaceutical areas. Recent developments in, for example, animal cloning, potentially impacting on farm animal breeding, have also attracted wide public interest. FDF is aware of the

establishment of expert committees to address a number of areas involving genetics, including human fertilisation and embryology, which address the ethical concerns which inevitably result from the scientific advances being made in this and other areas of medical research.

5.2 The ethics relating to genetic modification in food use have already been addressed by the Polkinghorne Committee, but the debate underlies all aspects of a technology perceived by some to be "playing God" or "tampering with Nature" and there is no single focus of this debate as it relates to food within the Advisory Committee system.

5.3 Ethical issues relating to food use therefore appear to receive inadequate attention and might usefully be addressed more comprehensively within the overall structure. Ethical issues should take into account a broad view. There should be a single body to advise Ministers, tasked with assessing views on sensitive ethical issues. The Nuffield Council is eminently able to handle such issues in a responsible manner.

5.4 As already stated above, FDF's main focus of attention lies in the work of the ACNFP and ACRE. FDF is aware of criticism that ACRE's current remit does not permit study of the general impact on the environment of an increasing number of releases of genetically modified crops, particularly where modified for herbicide tolerance or pesticide resistance. FDF supports the "case-by-case" approach to authorisiations for specific crop lines and products where they relate to food use, but sympathises with the view that a more holistic approach needs to be taken with regard to potential effects on the environment of growing a range of crops modified for tolerance or resistance to the same herbicide or pesticide and the implications for indigenous wildlife. However, genetic modification should be set in the context of an overall agricultural policy and practices. Many of the environmental concerns directed at GM are equally true of conventional farming practices. This debate is not simply about GM, but about what is needed from the UK agricultural industry in the coming decades.

5.5 FDF is also aware of concerns at the lack of mechanisms for considering GM policy as a whole where it relates to the food supply, and the suggested need for "an independent over-arching regulatory body" to strengthen oversight in this area[7]. The need for such a body became apparent in 1996 when the ACNFP and ACRE offered conflicting advice with regard to the presence of an antibiotic resistance marker in Novartis (Ciba-Geigy as it then was) Bt maize as it went through the process of authorisation under the Deliberate Release requirements and the then voluntary novel foods procedure. The matter was eventually resolved at EU level, but seriously dented public confidence in an already mistrusted system when confidence in the food supply chain was already at an all time low.

5.6 Moreover, the system with regard to authorisations for food use is somewhat piecemeal. We noted in our response to the House of Lords Select Committee on the European Communities' Sub-committee D Inquiry into the EC Regulation of Genetic Modification in Agriculture (memorandum of June 1998) that the lengthy procedures under the regulatory system often leave doubt as to whether or not a product has been authorised. We appreciate that changes in the UK Advisory Committee system cannot improve procedures established by legislation adopted at EU level, but might offer better co-ordination between the various Departments involved in the authorisation process as well as picking up issues which are not specifically attached to an individual authorisation but may impact on the wider and more general implications of an overall change in the food supply.

6. The Capacity of Government to be an "Intelligent Customer" for the Advice it Receives

6.1 The Government has at its disposal an extensive and well-established civil service which comprises personnel experienced in all areas of policy-making and includes, in appropriate departments, scientifically qualified staff who should be capable of assessing and, if necessary, interpreting scientific advice to Ministers. It is then a matter for Ministers to accept, reject or qualify the advice, as appropriate, in developing Government policy.

6.2 The Advisory Committees' role in the decision-making process should be kept in context. It was once famously stated that advisers advise, Ministers decide. Recommendations should be made in line with the Committee's remit, based on the best scientific advice. It is not the role of such committees to make recommendations on the basis of socio-economic or other factors, unless clearly within their terms of reference. If Ministers and the Executive consider that there are other factors to be taken into account, or if the science is uncertain, it should be clearly stated on what basis the decision was reached if it appears to contradict expert advice.

7. Summary

7.1 FDF welcomes the current review as a timely appraisal of the scientific advisory system in the light of much recent criticism of scientific advice and government decisions on the use of genetic modification in food. FDF regrets that recent media coverage has generated more heat than light by confusing the issues of protecting the UK environment from potential damage from the planting of GM crops with non-segregation of US-grown GM soya and its current use in food products. Half-truths peddled by the anti-GM lobby have

[7] Genetically modified plants for food use, The Royal Society September 1998.

been presented as fact and given additional credibility by constant repetition. The impartiality of expert scientific advisers has been called into question simply because they have been party to the authorisation of a GM product.

7.2 FDF considers it important that the Advisory Committee system in respect of food remains risk-based and draws on scientific evidence and experience, not political expediency. Much current opposition to the technology appears to be based on a "what if" scenario, despite there being no evidence of harm. Public acceptability will necessarily influence many developments in the field of biotechnology. It is important that current ignorance and mis-information be remedied via an authoritative and trusted system. If the current system is perceived as indequate or is not trusted, the situation must be remedied.

17 March 1999

APPENDIX 20

Memorandum submited by the Health and Safety Commission and the Health and Safety Executive

1. Introduction

1.1 *About this memorandum*

1.1.1 This memorandum presents the response of the Health and Safety Commission (HSC) and the Health and Safety Executive (HSE) to the request by the Science and Technology Committee for assistance in conducting a case study on genetically modified foods in the context of the Committee's inquiry into the Scientific Advisory System.

1.1.2 The memorandum is in 4 sections:

(1) an *introduction*

(2) an outline of the *role* of HSC/E in regard to genetically modified organisms

(3) our approach to, or views on, *specific issues* as requested, ie

— the adequacy and quality of scientific advice;

— the role and framework of advisory committees;

— the ability to respond to rapid scientific developments;

— whether there should be an overarching body to advise on and oversee all genetically modified food issues;

— the capacity of the Government to be an "intelligent customer" for the advice it receives;

(4) an update on HSE-led *research* on the solicitation and elicitation of expert advice.

1.1.3 More general information on what HSC and HSE are, what we do, and on our approach to risk is set out in a previous memorandum from HSE on the scientific advisory system itself.

1.1.4 If the Committee would like it, we would be very willing to provide further information.

2. Responsibilities of HSC/E in Regard to Genetically Modified Organisms

2.1 *About this section*

2.1.1 This section sets out the responsibilities of the Health and Safety Commission (HSC) and the Health and Safety Executive (HSE) in regard to genetically modified organisms (GMOs). It also sets out the limited responsibilities we have for genetically modified food.

2.1.2 Broadly our responsiblities on GMOs are to:

(a) operate and enforce the legislation on GMOs when used in *containment;* and

(b) assist in operating and to enforce the legislation on the *deliberate release* of GMOs.

2.1.3 A brief description of our role in each of these aspects follows.

2.2 *Contained use of genetically modified organisms*

2.2.1 Under the direction of HSC, HSE leads on and enforces the legislation in Great Britain that controls the safety, to humans and the environment, of activities involving genetically modified organisms (GMOs) *in containment.* Here containment means situations where the contact of the GMOs with humans and the environment is limited by the use of barriers so that harm is avoided. Barriers include such things as:

— laboratory facilities;

— animal houses used, for example, for breeding modified animals;

— fencing to restrain farm animals;

— plant growth rooms and glasshouses; and

— industrial fermentors used in, for example, the large scale production of enzymes for use in the food industry.

2.2.2 In operating the contained use legislation HSE works closely with other Government Departments with an interest in this area, especially the Department of the Environment, Transport and the Regions (DETR), Scottish Office, Welsh Office and the Ministry of Agriculture, Fisheries and Food (MAFF). Together, these Departments take the policy lead in environmental aspects of the contained use of GMOs.

2.2.3 All contained use activities are regulated under the Genetically Modified Organisms (Contained Use) Regulations 1992 [SI 1992 3217] as amended[8]. These Regulations (from now on referred to as "the Contained Use Regulations") are made jointly under the Health and Safety at Work etc Act 1974 [1974 c.37] (HSWA) and the European Communities Act 1972 [1972 c.68] (ECA).

2.2.4 The Contained Use Regulations implement the European Directive on the contained use of genetically modified micro-organisms (GMMs) [90/219/EEC]. However, the scope of the national legislation includes genetically modified animals and plants, and so is broader than that of the Directive which is limited to GMMs.

2.2.5 The Contained Use Regulations take a *precautionary approach.* In contrast to much health and safety legislation, the Regulations were not introduced in response to any incidence of actual harm to people from their work activities, or the effects of that work on others. Annex 1 contains a brief summary of the evolution of the national legislation on health and safety aspects of GMOs. This is of interest because it illustrates:

— that the UK was one of the first countries to introduce regulatory controls;

— the considerable degree of precaution built into the regulatory controls; and

— the subsequent involvement of the EU in shaping the control regime.

2.2.6 The *main requirements* of the Contained Use Regulations are:

— *risk assessment* of all activities involving GMOs. In the case of GMMs this involves consideration of risks to human health and safety (but excludes food safety—see below) and risks to the environment. So far as genetically modified animals and plants are concerned only human health and safety is considered (again excluding food safety);

— the establishment of a local *genetic modification safety committee* (GMSC) to advise on all risk assessments. These GMSCs are an important aspect of the local management system in the institutions undertaking genetic modification work;

— *notification* to HSE of all premises where contained use genetic modification activities are to be undertaken, including where GMOs are cultured, stored, used, transported, destroyed or disposed of. Where higher risk GMMs are involved this includes the requirement to obtain a consent from HSE.

— *notification* to HSE before higher risk activities involving GMOs are undertaken. In the case of GMMs, risk includes risk to the environment and human health and safety. Again, in certain cases a consent from HSE is required before work can proceed. For genetically modified animals and plants notification is only required in respect of work involving hazards to human health and safety;

— suitable and sufficient *containment* and *control measures* and appropriate *standards* of occupational and environmental safety.

2.2.7 We operate, therefore, legislation which covers both environmental and human health and safety aspects of contained use activities, involving such things as genetically modified animals, genetically modified crop plants and the production of enzymes which are used in the food processing industry. However, the Contained Use Regulations cover *only viable material*, ie live GMOs. So a whole genetically modified tomato fruit would be covered as the seed is viable, but tomato purée would not.

2.2.8 *Inspection and enforcement* of the Contained Use Regulations is undertaken by HSE's specialist biotechnology inspectors. Since the Contained Use Regulations came into effect 10 Improvement Notices and one Prohibition Notice have been issued. There has also been one prosecution.

[8] The amending regulations are: the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996 [SI 1996/967]; and the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1998 [SI 1998/1548].

The Contained Use Regulations and Food.

2.2.9 The Contained Use Regulations *do not cover food safety*—they are not even concerned with whether the GMO may be a food, or that its products may be used in food processing. The legislation focuses on whether the contained use activities involved present any risk to human health and safety, or to the environment. MAFF and the Department of Health (DH), operating under different legislation, are responsible for food safety, ie the safety of consumers. In due course these roles will transfer to the Food Standards Agency.

2.2.10 Our role under the Contained Use Regulations, however, does mean that we are responsible for operating and enforcing the regime which controls in the UK safety aspects of:

(a) the *research* and *early development* of products incorporating GMOs that may subsequently go on to be used commercially in food; and

(b) the *production* of, for example:

— enzymes for food processing which are produced from GMOs (eg chymosin used in cheese making);

— genetically modified crop plants grown in growth rooms and glasshouses; and

— (potentially at least)[9] genetically modified animals in animal houses or restrained by fences.

2.2.11 So far as genetically modified crop plants are concerned it would be normal practice for the initial stages of development of a new genetically modified variety to be conducted first in the laboratory, and thereafter to move to growth rooms and glasshouses. This would form part of the recommended step-by-step development procedure which ensures that risk assessment assumptions can be checked in controlled conditions, and that safety data can be collected. This information can then be used to support applications to test the plants in the environment under the deliberate release legislation (see section 2.4 below).

Forthcoming changes to the Contained Use Regulations

2.2.12 As mentioned above, the Contained Use Regulations implemented a European Directive. In October 1998 a major amendment to the Directive was agreed which will have to be implemented into national legislation by 5 June 2000. The key changes that will result are improved requirements in regard to risk assessment, improved containment and control measures and a more proportionate (to risk) targeting of administrative procedures. The culmination of an extensive process of *engaging stakeholders* throughout the negotiation and implementation of this directive will be the publication by HSC in May 1999 of a Consultative Document containing proposals to replace the current Contained Use Regulations.

2.3 *The Advisory Committee on Genetic Modification*

2.3.1 HSE services a network of advisory committees established by HSC by virtue of powers under HSWA. One of these is the Advisory Committee on Genetic Modification (ACGM). This committee was established by the HSC in 1984. Its current terms of reference are:

"to advise the Health and Safety Commission and Executive and the Secretary of State on all aspects of the human and environmental safety of the contained use of genetically modified organisms".

2.3.2 Like all HSC advisory committees, ACGM is constituted to be representative of the major stakeholder groups. The *constitution* of ACGM allows for four members to be nominated by employee organisations, four by employer organisations, and for four independent experts (one of which is reserved for a lay person). In addition, the committee has an independent chairman, currently Professor Kay E Davies, Professor of Human Anatomy at Oxford University. ACGM is also supported by a Technical Subcommittee which provides in-depth analysis of particular activities and plays a major role in the production of detailed, and highly respected guidance on contained use—the *ACGM Compendium of Guidance.*

2.3.3 The Compendium of Guidance, which is issued free to all institutions undertaking contained use activities with GMOs, includes detailed advice on such matters as good safety management, information and training, risk assessment, and containment and control measures.

2.4 *Deliberate release of GMOs*

2.4.1 We are one of the agencies and Government Departments involved in the operation of the legislation controlling the deliberate release and marketing of GMOs. Our role is twofold:

— consideration of *health and safety aspects* of applications to deliberately release GMOs into the environment; and

— *enforcement* of the deliberate release legislation under the terms of an Agency agreement between the SoS for Environment, Transport and the Regions and HSC.

[9] In fact we do not know of any genetically modified animals which have been used as food to date, although genetically modified salmon which are under development as a possible food have been grown in contained use facilities.

2.4.2 The legislation is made under the Enviroment Protection Act (EPA) and, like the Contained Use Regulations, also derives from a European Directive (in this case 90/220/EEC). DETR has the lead role in policy formulation and operation of the legislation. DETR has established its own advisory committee, the Advisory Committee on Releases to the Environment (ACRE).

2.4.3 As with the contained use legislation, deliberate release is only concerned with the safety (to humans and the environment) of viable GMOs.

2.4.4 In relation to genetically modified crop plants, which are being developed for potential food use, the main *health and safety issues* associated with deliberate release tend to centre on questions of allergenicity or toxicity in relation to workers who may come into contact with the GMOs. In the main these are research and agricultural workers operating the field trials. To date, the plants which have been assessed have not raised any significant human health and safety concerns.

2.4.5 *Inspection and enforcement* is undertaken by HSE's specialist biotechnology inspectors. A key aspect is to check that the agreed conditions which accompany all consents to deliberately release GMOs are being met in practice. The first prosecutions have just been taken. Monsanto plc and Perryfields Holdings Ltd were found guilty of contravening Section 111(1) of the Environment Protection Act 1990 and received fines respectively of £17,000 and £14,000.

3. Specific Issues

3.1 *About this section*

3.1.1 This section picks up the specific issues on which our approach, or views, were sought by the Select Committee. With the exception of section 3.5 (on the question of whether there should be an overarching body to advise on and oversee all genetically modified food issues) the section illustrates in the context of GMOs points made more generally in the previous memorandum from HSE on the scientific advisory system.

3.2 *The adequacy and quality of scientific advice*

3.2.1 In the memorandum from HSE on the scientific advisory system we set out our general approach to ensuring the adequacy and quality of scientific advice. We explained how we seek to put into practice the principles in the guidelines from the Chief Scientific Adviser[10]. In particular we seek to:

— *promote exchange of information* and add to HSC/E's corporate knowledge of hazard and risk;

— *open up issues to discussion and debate* early on in the process of informing and reaching decisions;

— submit scientific advice to *peer review and challenge.*

3.2.2 In the context of GMOs we do this by:

(a) maintaining an extensive *network of contacts:*

— *in academia and in industry.* Such networks are both formal as, for example, in HSC's Advisory Committee on Genetic Modification (ACGM), and informal. Both are important in providing the regulator with key information and intelligence about new developments in a rapidly developing industry;

— with the *Research Councils.* Again the networks are both formal (one of the employer representatives on ACGM is nominated by the Research Councils) and informal;

— between *Government Departments.* The formal arrangements include the group of officials (MISC(0)4) that shadows the Ministerial Committee on Biotechnology and Genetic Modification, chaired by Jack Cunningham, and the Interdepartmental Group of Officials on Genetic Modification and Technology (IGGMOT), which brings together policy officials at working level from all Departments with an interest. The Research Councils are also represented on IGGMOT, providing an additional linkage. In practice the day-to-day business of operating the Contained Use and Deliberate Release Regulations brings officials with responsibilities for genetic modification into very regular contact. The necessary arrangements are formalised in Memoranda of Understanding between Departments;

(b) *collecting and collating information* acquired from:

— the networks in (a) above;

— attendance at seminars and conferences;

— HSE's *specialist biotechnology inspectors* who draw on many years experience of work with GMOs in advising on technical aspects of policy and who undertake *inspections*—an invaluable source of information about what is actually happening "on the ground" in industry and in universities. The intelligence gathered is fed back into the policy system;

[10] *The use of scientific advice in policy making,* issued by the Office of Science and Technology, March 1997.

— *processing the notifications* received under the Contained Use and Deliberate Release Regulations, and acting on the intelligence received. An example is the incidental discovery of the rearing of genetically modified salmon under conditions which, without the intervention of HSE inspectors, may not have provided adequate containment and segregation from salmon in their natural breeding grounds;

— undertaking *research*. Examples include a recent review of gene transfer from GMMs and on-going research into novel genetically modified viruses;

— *investigaton of accidents and ill-health* arising from work with GMOs. The necessary arrangements to do this are in place, and there is a requirement in the Contained Use Regulations to report to HSE any unintended spillage with potential human health or environmental consequences. However, no such spillages have ever been reported and HSE is not aware of any instances of occupational ill-health attributed to work with GMOs. One spillage has been reported in the context of deliberate releases, but this did not pose a human health risk and the environmental risk was contained by additional control measures;

(c) *promoting discussion, debate, peer review and challenge* in various fora, including:

— *within HSE,* where inspectors, scientific and technical, and policy staff meet regularly to address health and safety problems (at working level and at the Board, which includes HSE's Chief Scientist and which considers and agrees all key HSE policies);

— *HSC* itself, which provides the policy steer for all HSE's work, and which is informed and advised by ACGM. HSC meets fortnightly. HSC advised ministers on the main negotiating line on the major amendment of the Contained Use Directive (see 2.2.12 above);

— within *ACGM and its Technical Subcommittee.* The Technical Subcommittee provides advice on novel and/or higher risk notifications. HSE's specialist inspectors provide the secretariat for the subcommittee. This not only gives the inspectors an understanding and insight into some of the best independent expert thinking on key issues, but also provides an important link between theory and practice;

— *EU and international fora* where experience of good (and not so good) practice can be shared. In this context feedback on the ACGM's *Compendium of Guidance* (para 2.3.2) has shown that its recommendations are *widely regarded as setting good practice* for contained use of GMOs. The Compendium has been widely distributed (eg to South Africa, Cuba, Hong Kong and Brazil) and has been adopted by other regulators;

(d) maintaining a policy of *openness:*

— in inviting all interested parties to *identify shortcomings* in the control regime for GMOs and in suggesting improvements. A particular instance was the engagement of all stakeholders in identifying the changes that were considered necessary to the 1990 EU Directives on the contained use of GMOs and in providing supporting evidence. This enabled HSE to approach the European Commission and helped to persuade them to bring forward a proposal to amend the Directive. *Engagement of stakeholders* continued throughout the negotiation of the amending directive (on which HSE led for the UK), and continues in the ongoing consultations on implementation. They will culminate in the Spring of this year with the issue by HSC of a *Consultative Document* which will include new draft contained use regulations. Our stakeholders include, of course, environmental groups such as Friends of the Earth and Greenpeace, although in general these groups are more concerned with deliberate release of GMOs than with contained use;

— *in developing guidance* such as the ACGM's Compendium, a process in which stakeholders are engaged in developing standards and good practice;

— *maintaining a public register* of notifications received by HSE. We intend to improve our procedures here when the new contained use regulations are in place;

— *placing on the Internet* the agendas of ACGM and HSC meetings in advance of the meetings themselves to enable any interested parties to contribute papers for discussion. After the meetings the information on the Internet is updated with summary outcomes. In addition full copies of the papers are available from HSE information centres (subject only to exemptions in the Code of Practice on Open Government).

3.3 *The role and framework of advisory committees*

3.3.1 The advisory committees that provide scientific advice in regard to our responsibilities for GMOs are:

(a) HSC's Advisory Committee on Genetic Modification (ACGM); and

(b) DETR's Advisory Committee on Releases to the Environment (ACRE).

3.3.2 The terms of reference and constitution of ACGM are set out in section 2.3. Like other HSC committees, it is constituted on a *multi-partite* basis. Experience has shown that such a multi-partite structure

has proved very successful in engaging the direct involvement of key stakeholders. ACGM reports to HSC which ensures further stakeholder involvement and enables the hazards and risks from GMOs to be considered within a wider framework of occupational health and safety. HSC sets ACGM's work programme, and receives and agrees its outputs.

3.3.3 ACGM's remit is coterminous with the Contained Use Regulations. We believe that the quality of the advice from ACGM is very high, as evidenced by, for example, the authoritative nature of its Compendium of Guidance, which is recognised not only in the UK but also internationally (see 3.2.2(c)).

3.3.4 We also receive some advice from ACRE, which is established under the Environmental Protection Act (EPA). Our interest here is the assessment of the safety aspects of viable GMOs where people may come into contact with GMOs that have been released into the environment (though not as food). In our experience ACRE's approach is very thorough and the quality of their advice is good.

3.3.5 The advice from ACGM and from ACRE is, quite properly, restricted to scientific matters within their terms of reference. It is for Ministers (and in the case of contained use of GMOs, HSC) to input on wider factors such as ethics, agricultural policy and biodiversity, leaving open the question of how this might best be effected for all activities involving GMOs. It is just these considerations that have prompted the question of whether there should be an overarching body to advise on and oversee all genetically modified issues (see section 3.5 below).

3.4 *The ability to respond to rapid scientific developments*

3.4.1 The ability to respond to rapid scientific developments depends on:

(a) picking up developments *early;*

(b) *commissioning research,* in particular anticipating the need for specific studies;

(c) being able to call upon a *broad range of scientific expertise;*

(d) good *communication* with other advisory bodies;

(e) a *legislative framework* that is sufficiently *flexible* to encompass new developments;

(f) up-to-date, *authoritative guidance* on risk assessment and control measures that supports the legislative framework.

3.4.2 In the context of our role on GMOs, and the Contained Use Regulations in particular, these requirements are met by:

(a) the formal and informal networks outlined in section 3.2.2 above;

(b) inclusion of future research needs as a standing item on ACGM's agenda;

(c) the wide expertise available to:

— HSC from the ACGM and its Technical Subcommittee. (In this respect the Subcommittee is constituted with the flexibility to co-opt additional experts when necessary.)

— HSE from the various sources mentioned in section 3.2.2;

(d) the well developed networks that operate between officials who provide the secretariats for other advisory bodies. Some advisory committee members sit on more than one body (for example, two members of ACGM are also members of ACRE); this provides useful coordination. Exchange of ideas, information and advice is also encouraged by Departmental assessors who attend advisory committee meetings;

(e) a legislative framework based on the approach in HSWA which puts a requirement on those who undertake contained use of GMOs to carry out a risk assessment and derive the appropriate controls. This avoids undue prescription and provides flexibility. However, such an approach requires the regulator to have a high level of scientific and technical competence to challenge duty holders (including where necessary Universities and eminent academics), and pull them up where their assessment of risk is less than rigorous or where the provision and maintenance of standards of health and safety is at best sloppy;

(f) ACGM's Compendium of Guidance and other guidance prepared by HSE, which provides advice on how to carry out a risk assessment and which sets out established good practice on the appropriate control measures.

3.5 *Should there be overarching body to advise and oversee all genetically modified food issues?*

3.5.1 The memorandum from HSE on the scientific advisory system explained that our risk-based approach to regulation and standard setting essentially involves taking *all the available scientific information* about a risk and *coupling* it with *policy judgements* about the appropriate approach to their control. Successful risk management requires action that addresses the ethical and other socio-political aspects of the risk, as well as the actual risk of physical harm.

3.5.2 HSC has expressed the view that there is a need for a mechanism to debate ethical and other aspects of social policy that arise from all genetic modification activities (though it recognises that the demand for such a debate is perhaps less for contained use than for other activities involving GMOs). There are several ways that such a mechanism could be realised. One approach (recommended by the House of Lords Select Committee on the European Communities[11]) would be the establishment of a strategic committee "to examine more general issues which arise from the use of genetic modification in agriculture and to plan policy as a 'seamless whole'", and "to establish principles by which the development and application of the technology should proceed." We do not, however, feel that it is for us to suggest the way forward.

3.6 *The capacity of the Government to be an "intelligent customer"*

3.6.1 The general procedures and mechanisms we use to:

— *identify the need* for scientific advice;

— *assess* the scientific advice we receive; and

— *use* the advice to inform decision making;

were set out in HSE's memorandum on the scientific advisory system.

3.6.2 In fulfilling our responsibilities in regard to GMOs we apply these procedures and mechanisms, and then *act* taking into account the advice we receive. Many aspects of our approach have already been mentioned in this memorandum. In summary they include:

(a) a largely *non-prescriptive, goal setting* approach that provides a regulatory regime which is adaptable to advances in technology;

(b) *high quality advice* from HSC's own advisory committee, the ACGM;

(c) commissioning *research* to fill gaps in knowledge and understanding;

(d) strong *scientific and technological expertise* within HSE as the regulator;

(e) the means to *bring together scientific and technological expertise,* and *inspectorial* and *policy* skills to address health and safety issues from GMOs;

(f) procedures that:

— *open up* issues to discussion and debate early on in the process of informing and reaching regulatory decisions;

— *exchange information* and *engage the stakeholders;*

— submit scientific advice to *peer review* and *challenge;*

(g) means to prepare and promulgate authoritative *good practice;*

(h) an *open approach* that seeks to engage stakeholders throughout a process of informing and reaching decisions on how risks should be addressed and on the standards that should be applied, and enlists their support in successfully implementing the outcome.

3.6.3 In addition, the Memorandum from HSE on the scientific advisory system outlined our *framework* for taking risk-based decisions (known as the Tolerability of Risk, or TOR framework) that enables all the available scientific information on the actual risk of harm to be coupled with policy judgements about the appropriate approach to addressing a risk problem.

3.6.4 We believe therefore that HSCE's capacity to be an "intelligent customer" for the scientific advice we receive is an essential element in enabling us to fulfil our regulatory responsibilities.

4. THE SOLICITATION AND ELICITATION OF EXPERT ADVICE

4.1 *Update on research*

4.1.1 HSE's Memorandum on the scientific advisory system concluded by noting that we are not satisfied that our procedures for securing scientific advice are always as robust as they might be, and that we proposed to undertake further work.

4.1.2 Since then considerable progress has been made. In particular HSE has:

— secured the support of HSC for the project, who suggested that their Advisory Committee on Toxic Substances (ACTS) might provide a useful case study;

— attracted co-sponsorship from the Office of Science and Technology, the Cabinet Office Better Regulation Unit, the Scottish Office, MAFF, DH and DETR;

— secured the support of the Government's Chief Scientific Adviser;

[11] *EC Regulation of genetic modification in agriculture.* Select Committee on the European Communities, House of Lords, Session 1998–99, 2nd Report.

— established a steering group for the project. The steering group is chaired by Dr Jim McQuaid, HSE's Chief Scientist, and includes a representative of each sponsoring Department;

— put in hand a two stage competitive tender exercise to select a suitable contractor. Invitations to tender appeared in the national press last November, and triggered a large response;

— managed the selection process. In the first stage a shortlist of four potential contractors was selected on the basis of the quality of submitted outline proposals. In the second stage a final selection was made on the basis of full written proposals and interviews, at which those shortlisted gave brief presentations on their approach.

4.1.3 At the time of writing this memorandum (late February/early March) a contract with the successful contractor for a significant research project on the solicitation and elicitation is being drawn up. The research will first:

(a) undertake a mapping study to:

— identify and categorise *current practices* within Government for soliciting and eliciting expert scientific advice, and incorporating it into policy; and

— *review* what is known generally about the relationship between how expert scientific advice is incorporated into policy and the quality, or perceived quality of the decisions made;

and then

(b) probe in greater depth and to draw our *principles of good practice* (including how to avoid pitfalls) for:

— the *engagement of scientific experts* (ie selection, remit, independence, etc);

— the *elicitation of their advice* (ie framing of issues, support provided, avoidance of bias, characterisation and reporting of uncertainty, resolution of conflict, presentation of advice, etc); and

— the *incorporation of expert scientific advice* in the wider decision making process.

4.1.4 The *aims* of the project are to:

(a) *identify good practice* for soliciting and eliciting expert scientific advice;

(b) *provide a sound framework,* based on the dominant assumptions of openness and transparency, on which the Government can assemble authoritative expert scientific advice that is robust when exposed to public scrutiny and peer review;

(c) *enhance trust and confidence* in the processes of risk assessment, management and communication by:

— opening up to public scrutiny and peer review the expert advice elicited;

— exposing and explaining the assumptions made and the uncertainties that pervade both the assessment of risks and the effectiveness of possible risk management options;

— making clear where expert judgement has been applied to convert information and expertise into intelligence about risk problems, or where uncertainties are so large that the expert advice is essentially a matter of opinion;

— adopting suitable procedures to engage as appropriate both stakeholders and experts; and

— explaining how expert scientific advice, together with the relevant sociological, economic and political considerations, contributed to the final decision made.

4.1.5 We hope the project, which is due to last 15 months, will start at the beginning of April 1999.

Annex

A brief outline history of the legislation on health and safety aspects of GMOs

1. Following the discovery of the structure of deoxyribonucleic acid (DNA), significant advances in biotechnology in the early 1970s culminated in the successful introduction of genetic material from one organism into another (bacteria) in which it could not occur naturally. Concerned at the perceived potential consequences of the new technology, some influential scientists called for a voluntary moratorium on any further work on genetic modification until the necessary hazards and risks had been explored and safe systems of work devised. These calls were reinforced in 1975 at the Asilomar Conference in California, which proposed that:

— certain genetic modification work could proceed provided strict precautions were adopted;

— the moratorium should remain for other work until the necessary safeguards were agreed; and

— some types of experiment should not be allowed under any circumstances.

2. At the time, genetic modification was only possible in the laboratory, and the perceived risks were to research workers.

3. The UK was one of the first countries to respond with a regulatory strategy. In 1974 a working party led by Lord Ashby recommended that genetic modification techniques should be allowed to continue but with rigorous safeguards. The working party concluded that genetic modification would provide "substantial (though unpredictable) benefits", and concluded that "it is not inconceivable that the technique might ultimately lead to ways to cure some human diseases known to be due to genetic deficiency." Lord Ashby's report was followed in 1975 by a report by Professor Williams, which contained a Code of Practice and recommended laboratory containment measures for genetic modification work. The Williams Report also recommended that there should be a statutory requirement that work involving genetic modification should be notified to HSE (which had just been established under HSWA).

4. In 1976 the Medical Research Council set up the Genetic Manipulation Advisory Group (GMAG). HSE and other Government departments were involved in its operation. GMAG issued guidance on risk assessment and an appropriate laboratory containment and other controls.

5. The "rigorous controls" recommended in the report of the working party chaired by Lord Ashby and in the Williams Report were introduced as The Health and Safety (Genetic Manipulation) Regulations 1978. Any activity involving genetic manipulation had to be notified to GMAG and to HSE. GMAG was reconstituted as an HSC advisory committee. The 1978 Regulations covered only risks to people.

6. In 1984 GMAG was replaced by the Advisory Committee on Genetic Modification (ACGM). Its remit was the safety of GMOs used in containment, and the focus of its work was the health and safety of people. The non-statutory guidance issued by ACGM did, however, extend the requirement for risk assessment to include an assessment of the risks to the environment.

7. Through the 1980s the techniques of genetic modification were developed into industrial processes, and it became apparent that the very precautionary approach adopted in the 1978 Regulations was unduly restrictive and disproportionate to the risks as revealed by the increased knowledge gained. The 1978 Regulations had become out of date and were replaced by the Genetic Modification Regulations 1989. Like the 1978 Regulations, they applied only to human health and safety and not to the protection of the environment (though under the auspices of HSC and ACGM there was a voluntary agreement with the industry that they would also assess environmental risks). However, the 1989 Regulations did cover both contained use and deliberate release, and they gave statutory force to ACGM's system of classifying genetic modification work on the basis of four levels of hazard and risk. The all embracing requirement on notification was relaxed to catch only premises and activities using GMOs in the upper two levels of the classification system. The classification system and the allocation of activities within it, however, remained precautionary.

8. EU interest in harmonised legislation on GMOs started in the late 1980s, and in 1990 two new directives were agreed—90/219/EEC on contained use and 90/220/EEC on deliberate release. In the UK this led to a split in the control regimes:

- the requirements for contained use (including associated environmental aspects) were implemented by HSC/E as the Genetically Modified Organisms (Contained Use) Regulations 1992 using powers in HSWA and the European Communities Act 1972. In operating these Regulations HSC continued to look to ACGM for expert advice; and
- the requirements for deliberate release (including associated health and safety aspects) were implemented by DETR using the provisions of the Environment Protection Act 1990 (EPA). To help operate these provisions DETR created a new advisory committee, the Advisory Committee on Releases to the Environment (ACRE).

9. The EPA, therefore, was the first national legislation to address deliberate releases of GMOs to the environment.

10. At the time when Directives 90/219 and 90/220 were being negotiated many other Member States did not feel able to accept fully the somewhat more relaxed approach in our 1989 Regulations for contained use, and the outcome included a stricter notification requirement as well as the inclusion of a more holistic requirement on risk assessment covering risks to people and the environment. Some appropriate adjustments to these provisions are, however, included in the major amending directive that has recently been agreed (see section 2.2.12).

Glossary of Acronyms

ACGM	Advisory Committee on Genetic Modification
ACRE	Advisory Committee on Releases to the Environment
DETR	Department of the Environment, Transport and the Regions
DH	Department of Health
ECA	European Communities Act 1972
EPA	Environment Protection Act
EU	European Union
GMAG	Genetic Manipulation Advisory Group
GMM	Genetically modified micro-organism
GMO	Genetically modified organism

GMSC	Genetic modification safety committee
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HSWA	The Health and Safety at Work etc Act 1974
IGGMOT	Interdepartmental Group of Officials on Genetic Modification and Technology
MAFF	Ministry of Agriculture, Fisheries and Foods
SoS	Secretary of State

17 March 1999

APPENDIX 21

Memorandum submitted by Friends of the Earth, England, Wales and Northern Ireland

SUMMARY

The scientific advice currently available to Government on genetically modified (GM) food and crops is inadequate because it comes from a small body of experts on the advisory committees who are predisposed to approve applications.

The decisions made about GM food and crops should also consider questions of ethics and need and not just science.

The advisory framework needs to be revised to ensure that all evidence is challenged and independently verified and to include active participation of the public.

The present system fails to cope with rapid scientific developments because the advisory committees are too narrowly based both in terms of remit and membership.

Reluctance to apply the precautionary principle means that unnecessary risks are being taken with the environment and food safety.

Active public participation in the decision making process is more important than the establishment of an overarching body.

Public participation will enable Government to make decisions based on broader considerations than just science.

1. INTRODUCTION

Friends of the Earth (FOE) exists to protect and improve the conditions for life on Earth, now and for the future.

Friends of the Earth is one of the largest international environmental networks in the world, with over 50 groups across five continents:

- one of the UK's most influential national environmental pressure groups;
- a unique network of campaigning local groups, working in 250 communities throughout England, Wales and Northern Ireland.

Friends of the Earth have been campaigning about food and agriculture since the early 1980s. The current Campaign for Real Food was launched in May 1997 following increasing concern over the rapid introduction of genetically modified food and crops into the UK. We are supporting the Five Year Freeze Campaign which is calling for a minimum five year moratorium for:

1. the growing of genetically engineered crops for any commercial purpose.
2. imports of genetically engineered foods and farm crops.
3. the patenting of genetic resources for food and farm crops.

During the Five Year Freeze the following must be developed:

- A system which allows people to exercise their right to choose products free of genetic engineering
- Public involvement in decisions on the need for and the regulation of genetic engineering
- Prevention of genetic pollution of the environment
- Strict legal liability for adverse effects on people or the environment from the release and marketing of genetically modified organisms
- Independent assessment of the implications of patenting genetic resources
- Independent assessment of the social and economic impact of genetic engineering on farmers

Friends of the Earth has been involved in several cases relating to GM crops and foods in which our opinions and advice have been forwarded to Government and the Advisory Committees. In addition, the

experience of a large number of FOE members in their attempts to participate in the advisory process provides FOE with a unique perspective on the failings in the current system. The following document outlines our concerns and recommendations based upon this experience.

2. The Adequacy and Quality of the Scientific Advice

Scientific advice to government has to be seen to be impartial and independent. In our view this is not the case when it comes to the Advisory Committee on Releases to the Environment (ACRE) or the Advisory Committee on Novel Foods and Processes (ACNFP). Both committees rely far too heavily on the biotech industry's own data and risk assessments, many of which have not been independently reviewed, when advising ministers under the Environmental Protection Act 1990 and the Genetically Modified Organism (Deliberate Release) Regulations 1992 and the Novel Food Regulations 1997.

The Advisory Committee on Releases to the Environment

ACRE frequently give the impression of being impartial and biased in favour of the biotech industry. For example, it was at their behest that the "fast track" system for applications to release certain GM crops into the environment was introduced. This procedure effectively removed the public's right to participate in the decision making process and introduced a "rubber stamp" approach to the evaluation of many applications. To date, ACRE have not turned down a single application to release a GM crop into the environment.

ACRE's recent advice on Monsanto's Maize (97/M3/2) illustrates an apparent partiality in favour of applicants (a critique can be found in Annex 1). The minutes of the meeting held in January 1999 highlight that the committee was well aware of the shortcomings of the application but still advised the Minister that it should be approved!

The ACRE has been asked on several occasions to review their previous advice to the Minister following publication of scientific evidence relating to the potential for harm caused by GM organisms. For instance in the case of Novartis's Bt Maize, new research published last year showed that lacewing larvae could be harmed by the Bt toxin when feeding on prey. ACRE's response was that although the research was well designed they felt it gave insufficient reason to change their previous advice that the maize should be approved (see FOE letter in appendix 2)[12]. In 1998 ACRE were also asked to review the risk of cross pollination of an organic farmer's sweet corn with GM maize in Devon, and in 1999 ACRE reviewed Plant Genetics Systems' marketing application for spring oilseed rape in light of new evidence on cross pollination with neighbouring crops and wild relatives.

In all these cases, Friends of the Earth's view was submitted to the Department of the Environment Transport and Regions (DETR) and ACRE (copies included in appendices 3 and 4)[13] FOE submitted that the scientific evidence supported the use of the precautionary principle, but in each case ACRE chose to advise the Minister that the new evidence did not give them cause to change their original opinion—decisions that suggest that ACRE is more interested in defending its initial view rather than advising the Minister on the degree of scientific uncertainty that exists.

ACRE also lacks expertise in several key areas. The committee has no soil scientist, no expertise in long distance pollen movement, no farming representative (practical or academic), no ethical adviser and no consumer representative. In fact, eight out of 13 of the current members have clear links with the biotechnology industry (see Annex 2). One member has even worked on a MAFF contract to investigate methods to persuade members of the public as to the benefits of GM food and farming (Development of a Strategy to Promote the Public's Understanding of Biotechnology, MAFF project conducted by Sheffield University, July 1998).

The Ministers should be able to call on other experts when the need arises. For example, in the case of the organic farmer Guy Watson, which related to pollen flow from GM crops, advice was given by ACRE despite the fact that none of them has any expertise in this area. When there is concern expressed from outside ACRE, the Minister should consult more widely and treat advice from experts outside ACRE with equal weight to that from the committee.

The Advisory Committee on Novel Foods and Processes

The ACNFP also bases its advice on very limited industry supplied data. The advice on Monsanto's Roundup Ready Soya provides a good illustration. Examination of the dossier supplied to the committee reveals that the ACNFP's decision was based on short-term "wholesomeness" trials on rats, catfish, chicken and cows. No toxicological studies on the whole GM food were supplied, no human feeding trials, no research into other physiological or biochemical effects were submitted, such as effects on the immune system or endocrine system and no data were supplied from trials when soya had been treated with glyphosate. In many cases, the ACNFP appears to accept poor quality evidence. In the case of composition analyses, comparisons

[12] Not printed.
[17] Not printed.

between varieties grown in different countries or different years. This means that any differences are almost certain to be masked by these other factors—such procedures would not be acceptable for any published research article, but appears to be permitted when assessing the safety of GM foods for consumption by the general population.

ACNFP should not be the sole source of advice for ministers on food safety. The voices of the consumer and ethnic communities of the UK are not well represented on the committee.

The use of the concept of "substantial equivalence" as a basis for the assessment of food safety is also of great concern. Comparisons based upon the measurement of known composition has severe limitations, in particular such an approach would be unable to detect unknown anti-nutrients and toxins produced as a result of modification, especially in less well known crops. We agree with the evidence given by Professor James and Dr Chesson, of the Rowett Research Institute, before the Committee on 8 March that the use of substantial equivalence is not adequate for the purpose of assessing the safety of GM foods.

It is essential that both the ACNFP and ACRE are reformed by revising their remits and membership. Members of advisory committees should be asking challenging questions of industry and refusing to approve applications until adequate answers, backed by independent research, have been provided.

3. The Role and Framework of the Advisory Committees

The FOE response to the DTI's consultation on the framework for overseeing biotechnology is appended (Appendix 5). This covers our views on the role and framework of the advisory system. We would like to emphasise the gaps in the current system.

- The ethics of a particular modification or release are not adequately covered.
- There is no system for assessing the economic and social consequences, such as impacts on farmers and the rural community.
- There is no opportunity under any of the regulations relating to genetically modified organisms or micro-organisms for the public to make any input which will influence the approval process.
- Liability for harm caused to human health, the environment or economic damage is not considered.

The risk assessments for releases into the environment or health impacts have a number of short-comings which are listed below:

- The indirect effect of releases into the environment are not adequately assessed because no single body has responsibility for assessing the impact of full-scale commercial use of a genetically modified organism (GMO) and associated chemicals.
- The long-term effects of releases are not adequately assessed nor supported by relevant research. For instance, issues relating to cross pollination and the resulting impacts on wild relatives of crop plants are frequently poorly researched or supported by relevant literature. Indirect effects, such as the impact on biodiversity of the prolonged use, season after season, of broad spectrum herbicides are ignored.
- The long-term health effects are not considered, or tested for.
- Risk/benefits analysis is poor and often only examines a narrow range of options. For example, herbicide resistant crops have only been compared with conventional intensive crops—ignoring the range of other agronomic options available in different farming systems, from the use of weed thresholds for herbicide reduction to organic practices.
- There is a lack of baseline knowledge about the environment into which the GMO is being introduced, in particular the ecology of agricultural systems and of soil living organisms. How can adverse effects be detected if there is an incomplete understanding of the ecosystem into which the GMO is being introduced?
- Lack of completed research concerning potential health impacts of releases, for example horizontal movement of genes from GMOs to gut micro-organisms. This means that risk assessments are made based upon insufficient information, and must be frequently based upon theoretical assumptions instead.
- Research into the risks associated with the release of GMOs is being conducted after they are released rather than before.

The role of the Advisory Committees must be to act in the public interest, and to be seen to do so. Recently the chair of the ACNFP, Professor Janet Bainbridge, has appeared in the broadcast media and on public platforms speaking in favour of GM food and attacking opponents of this technology, for example at the Food Future Meeting in Leeds on 17 October 1998 and at a seminar organised by Durham County Council on 18 February 1999. In her evidence to the House of Lords European Communities Committee (Sub-Committee D), Professor Bainbridge gave the following opinion:

> I understand that at the moment a moratorium would be illegal anyway, but leaving that aside, I think it would be tantamount to saying "We are not really sure so we had better step back and had better stop this work, we had better stop the progress of the research and the development of

applications". I think at the end of the day we have to be minded about issues like industrial competitiveness and economic concerns. ((Q716)

The role of the chair of the committee should be to act as the public's watchdog, not as an additional spokesperson for industry, as Professor Bainbridge is appearing to do.

Another area of concern relating to the commercial development of GM crops is the secrecy involving approval of pesticides for use on them. The Pesticide Safety Directorate (PSD) and the Advisory Committee on Pesticides (ACP) make decisions without any reference to members of the public and the wider scientific community. The approval of pesticides has been shown to be flawed, for instance a monograph by the Austrian Ministry of Agriculture on the pesticide lindane has just revealed that there are very significant gaps in the data relating to a host of potential environmental and health effects (the Monograph was produced by the Austrian Federal Ministry of Agriculture for the EU to assess the inclusion of lindane in Annex 1 of the EC Directive 91/414/EEC). Lindane was approved for a further five years in the UK in 1996. Whether these gaps in data were recognised and ignored by PSD and ACP is not clear because their deliberations were not made public.

There are already applications for registration of herbicides designed to be used with GM crops. There is no opportunity for any organisation or other scientists to make representations on these applications. There is no opportunity for public comment or participation until after the decision has been made, at which point there is no opportunity for appeal. This is completely unsatisfactory.

4. The Ability of the Current System to Respond to Rapid Scientific Developments

The Minister has the power under Article 16 of the 90/220 Directive to revoke marketing consent for any GM crop or products if new scientific evidence emerges. So far there has been a reluctance to use this power in the UK despite statements from Ministers that they will use the precautionary principle when assessing the safety of GM food and crops. Part of the reason for this reluctance is the inability of the advisory committees to significantly revise their previous advice. The inertia of the advisory committees has acted as a serious block on effective responses to new developments.

Do we need an overarching body to advise and oversee on genetically modified food issues?

The gaps in the present advisory system have been identified in the section above. If these gaps are adequately filled by giving ACRE and ACNFP revised remits and more balanced and independent membership, the need for an overarching body is less obvious. What is more important is that ethics and need are brought more strongly into the regulatory process for releases to the environment, food safety, pesticide approval and seed approval.

At present, it is clear that the Government is not in receipt of sufficient information to make a balanced decision. One of the clearest remaining gaps is the lack of meaningful input from the public on the need and ethics of the use of GM food. Our views on how the public should participate in decision making were included in the response to the DTI consultation which is appended (Appendix 5)[14]. There is nothing more personal than what you eat and therefore public involvement in this key area of decision making is vital.

The role of a national overarching body is therefore unclear. There are gaps to be filled in the present system but there are risks that if another body is set up the public's views will be ignored as they are at present. It is FOE's view that the priority at present should be to make the present system more democratic and make use of public panels to assess applications, looking at the science as well as the ethics and need, as well as scientific committees. There is also a risk that any overarching body could be dominated by industry in the way ACRE and ACNFP have been and so consequently fail to command public respect.

In the end it is Government which has to make the decisions as to what is or is not safe to eat or release into the environment and what releases can be justified, based on good information and advice. What is an issue at present is not just where their advice comes from but the breadth and quality of the information they receive.

5. The Capacity of the Government to be an "Intelligent Customer" for Advice

Although genetic modification is a very complex issue, food is a basic and fundamental part of everyone's lives. Decisions about the future composition of our food cannot be based on the advice of scientists alone or on the narrow perspective of how the economy should develop. There are crucial ethical, social and economic issues which also have to be considered.

Under the present regulatory system we are far too reliant on industry to tell what is and is not safe. Scientific advice is now taken with a pinch of salt by many people following assertions about food safety in the past which proved to be untrue.

[14] Not printed.

The precautionary principle is the best one to follow in current circumstances, when scientists do not agree even about the basic assumptions on which the biotechnology is built. Many of the decisions to be taken are political, as they affect how society, the rural economy and the environment will develop. Such decisions should be taken by Government listening to the population at large. The proposals we have set out will enable the Government to take wider counsel than merely scientific opinion. In the long term this will make it more likely that the right decisions about the future direction for food and farming will be made.

17 March 1999

Annex 1

CRITIQUE OF A RECENT ACRE DECISION

The ACRE committee have very recently begun to make minutes of their meetings available to the public, and these clearly show that the committee is failing to give Ministers competent advice.

In their meeting dated 13 January 1999, ACRE considered an application for marketing consent put forward by Monsanto for genetically modified (GM) herbicide tolerant maize. In the minutes of the meeting it is reported that ACRE considered the initial application to have been inadequate, in that the analysis of molecular data was wrong. They concluded that "a lack of rigour. . . .and poor interpretation of data had contributed to a standard well below that required and expected in applications to place products onto the market"[15]. The committee also noted the applicant had made conclusions which were not justified by the data, and that the risk assessment had failed to consider a possible effect of the inserted gene on the host organism. In respect of this point it is stated that the committee came "to a view in the absence of the applicant's assessment". Although the animal feeding study "was not a classical toxicology test" ACRE felt that it showed that the GM food was safe for consumption.

Despite all these deficiencies, ACRE's advice to the Secretary of State was that the GM maize posed no greater risk than other maize. In other words, ACRE gave a positive response to a marketing application which was clearly below standard and missing relevant data upon which to make a reasoned judgement. The committee's approach appears to have been to make assumptions about the safety of the GMO when evidence is missing, and to come to conclusions based upon evidence which they accept is inadequate.

Annex 2

DETAILS OF BIOTECHNOLOGY INDUSTRY CONNECTION OF THE ACRE COMMITTEE

Name	*Associations*	*No of Applications*	*No of Test Sites*
Prof John Beringer	Member of Council of the Natural Environmental Research Council	4	5
Dr Philip Dale	Senior Research Scientist at John Innes Centre. He heads a department focusing on genetic engineering of oilseed rape.	2	2
Mr John Macleod	Director of National Institute of Agricultural Botany. NIAB is conducting the National Seed List Trials.	1 (by NIAB) 11 (for National Seed List Trials)	1 (NIAB) 163 (for National Seed List Trials)
Prof Nigel Poole	External and Regulatory Affairs Manager at Zeneca Plant Science, a leading Biotech Co	6	6
Dr David Robinson	Principal Research Scientist at Scottish Crop Research Institute, Advisor to Nickerson Seeds	5 (SCRI) 12 Nickerson N	9 (SCRI) 12 Nickerson N
Dr Ingrid Williams	Leader of the Insect-Plant Interactions Group, Institute of Arable Crop Research	1 (since joining ACRE in 1996)	3

In addition to the above the following two Committee members are directly involved in genetic engineering companies.

Dr Ian Garland: Assistant Director of Research at PPL Therapeutics, the makers of Dolly the sheep.

Professor David Onions—Consultant to Q-One Biotec.

[15] DETR Advisory Committee on Releases to the Environment. Minutes of the Fifty-Sixth Meeting 13 January 1999. Item 2.1.

APPENDIX 22

Memorandum submitted by Consumers' Association

SUMMARY

The system for providing advice on genetically modified (GM) foods currently takes too narrow an approach. The advisory committees have narrow, technical remits and many broader issues are not addressed. We would welcome the establishment of an over-arching advisory committee to ensure greater co-ordination and a more comprehensive, pro-active approach.

The system is primarily focused on individual products and works on a case-by-case basis using the principle of "substantial equivalence". Therefore, broader safety aspects including the potential for unintended consequences have not been adequately considered.

The system is unable to deal with the uncertainty that surrounds GM foods. It needs to take more of a precautionary approach to assessing and approving GM foods. Until the system is overhauled no further GM food products should be allowed on to the market.

This precautionary approach requires much greater consumer involvement in decisions about GM foods. Currently, there is a lack of consumer input into the advisory system and as a result policy has failed to reflect consumer concerns, including the ethical aspects of genetic modification, choice and the need to ensure that there are no adverse consequences in the long term.

The system has failed to anticipate and keep pace with developments, as highlighted by the failure to segregate GM crops, the inability to trace ingredients throughout the food chain and to monitor their long-term impact. There has also been a lack of debate about future uses of the technology such as the genetic modification of animals and the potential use of human genes in foods.

The system needs to become more open and transparent so it is clear what assumptions and judgements have had to be made and so that it is clear what research decisions have been based upon.

These concerns also need to be addressed within the scientific advisory system at European and international level as this is increasingly where decisions have to be made and where UK policy will be scrutinised.

INTRODUCTION

1. Consumers' Association (CA), publishers of *Which?, Health Which?* and other consumer books and magazines, is an independent consumer organisation with over 700,000 members.

2. As you will be aware, CA has already submitted evidence to this Inquiry of a more general nature. This memorandum supplements our earlier submission (June 1998) which made many references to genetic modification to illustrate our more general concerns.

3. We have closely followed the development of genetically modified food as it is an issue of great concern to many consumers. A copy of our policy report *"Gene Cuisine—a consumer agenda for genetically modified foods"*[16] which sets out our concerns in more detail than is possible in this memorandum is enclosed for the Committee's information. In addition, *"Confronting Risk—a new approach to food safety"*[17] which considers the current approach to risk analysis when making food policy decisions, and the changes we consider are necessary at UK, European and international level is included, together with our recent response to the Government's consultation on the framework for overseeing developments in biotechnology[18].

NEW CHALLENGES

4. Genetic modification in food production is a new technology. In addition to human health concerns, it raises other concerns such as environmental safety and ethical issues and these have become entangled. For example, changes in agricultural practices resulting from the introduction of GM crops may have implications for the nutritional quality of our diets in the future. Similarly, concerns about how to ensure that the technology does not adversely affect biodiversity, can also have implications for ensuring traceability and therefore safety throughout the food chain. It has also demonstrated that we increasingly have to make decisions when faced with scientific uncertainty and has also shown the global nature of food risks.

5. But the current scientific advisory system is not able to deal with such challenges. It is primarily focused on assessing the short-term consequences of changes to food production, rather than considering the broader, long-term implications.

6. Approval of GM products for food use falls between different advisory committees depending on whether the consequences within the laboratory, within the field, or on the shelf are being considered.

[16] Not printed.
[17] Not printed.
[18] Not printed.

Similarly responsibility falls between the Department of the Environment, Transport and the Regions (DETR) and the Ministry of Agriculture, Fisheries and Food (MAFF), and will soon be partly transferred to the Food Standards Agency which will report to the Department of Health (DH). Four committees have the main responsibility for control of biotechnology developments in the food chain: Advisory Committee on Genetic Modification (ACGM); Advisory Committee on Releases to the Environment (ACRE); Advisory Committee on Novel Foods and Processes (ACNFP); and Food Advisory Committee (FAC).

7. Control of biotechnology also increasingly lies with the European Union (EU). At a European level, the Scientific Committee for Food (SCF) has main responsibility. At international level, the Food and Agriculture Organisation and World Health Organisation Joint Expert Group on Food Additives (JECFA) which advises the Codex Alimentarius Commission also has an important role. This was highlighted by the recent controversy surrounding its advice on the genetically modified growth hormone, Bovine Somatotrophin (page 13 of *"Confronting Risk"* provides further details of this issue).

Our concerns about the current approach are summarised in the following paragraphs:

Adequacy of the current approach

8. Narrow remits—The committees involved have specific, technical remits that deal with a certain aspect of the technology, for example, the ACNFP deals with approval specifically for food use, while the FAC deals with labelling aspects. No body has responsibility for examining the implications of biotechnology as a whole and for the development of a coherent strategy taking all factors into account, from the laboratory to the food chain, or to evaluate fully both the short-term and long-term implications. There is no clear mechanism for anticipating and assessing the broader consequences of the use of the technology before products have been developed. Products are approved on a case-by-case basis which does not allow a sufficient examination of the broader implications of their use, such as possible interactions with other GM products, their impact on the ecosystem and on agricultural practices.

9. Short-term approach—In most cases, decisions about whether or not to approve a product are based on short-term studies, provided by the companies that have developed the product. There is a lack of independent research to verify the possible risks and benefits of these foods. Our earlier submission (paragraph 16–19)[19] outlined our concerns about the research base. There is also a lack of research into the long-term implications of the introduction of GM crops and foods. The scientific advice has focused on the product, for example, a specific crop, food or ingredient, rather than on the implications of the technology overall. This is demonstrated by the case-by-case approach that is taken and the use of the principle of substantial equivalence. Foods that are considered to be substantially equivalent do not have such a rigorous assessment. This also fails to acknowledge the potential for unintended and unpredictable side effects and to accept that many consumers' concerns are founded on whether or not the technology has been used, rather than whether the composition is any different from a standard equivalent.

10. Uncertainty—The scientific advisory system does not openly acknowledge the uncertainties inherent in any assessment of GM foods or any inevitable assumptions that are made. Judgements rather than scientific conclusions often lie behind decisions about whether or not to approve a product. Decisions are presented as though based on conclusive scientific evidence when this is not the case. This approach contrasts with a recent Cabinet Office commissioned MORI poll into public attitudes to risk which found that 80 per cent of respondents agreed (or tended to agree) that when unsure of the facts, the Government should nonetheless publish what information it has available. After Bovine Spongiform Encephalopathy (BSE), merely claiming to have conducted a risk assessment is not alone enough to reassure the public of food safety.

11. Ethical aspects—The current approach also fails to sufficiently acknowledge the ethical aspects of genetic modification. Although a committee was chaired by Reverand Polkinghorne to consider the ethical aspects of genetic modification and to advise the Government, ethical considerations are not explicit within the remits of the advisory committees. The technology is also moving at a rapid pace, yet the ethical dilemmas that this poses have not been debated and reconsidered.

12. Anticipating future developments—With its emphasis on a case-by-case approach, the current committees are not in a position to consider future developments in this field and advise the Government on any necessary action. Genetic modification of animals and of fish will cause greater concern for consumers than genetically modified plants. The use of human genes in food production will also be unacceptable to many people. However, there has not been sufficient consideration of the implications of these developments, such as whether they would be acceptable under any circumstances and how they could be controlled and traced.

13. Lack of transparency—A more fundamental problem is the lack of openness in the way that scientific advice is provided. This makes it difficult to evaluate the quality of the advice. As outlined above, the uncertainties that remain are not made explicit. This makes it difficult for consumers to trust the advice that is given and to make up their own minds about the risks and benefits that it poses. Although some steps have been taken to open up the advisory committees, for example, ACRE does produce a newsletter, these do not

[19] Not printed.

go far enough. As is the case more generally within government, commercial confidentiality can be used as an excuse to prevent disclosure of information that is in the public's interest.

14. Lack of consistency—There have been examples of specific products (a variety of maize and a potato, which both contained antibiotic-resistant marker genes) where different conclusions about whether to give approval to a product have been reached by UK and EU committees, although based on the same scientific evidence. This highlights the assumptions and judgements that have to be made even in a supposedly objective risk assessment. It also raises concerns about the expertise available to these committees and how this may influence the approach taken by a committee and the extent to which precaution is exercised. A multi-disciplinary approach is essential, as is the need for public interest representatives to sit on the committees.

15. Consumer representation—Consumers have not been adequately involved within the scientific deliberations, even though in many cases there is insufficient scientific evidence upon which to make a fully scientific assessment. Where consumer representatives have been appointed to the advisory committees, this has not been done openly and transparently. The value of effective consumer representation is discussed in more detail below.

16. Slowness to react—As well as a failure to anticipate future developments, there has also been a slowness to respond to new developments. For example, segregation of GM crops and traceability throughout the food chain. These issues have had to be addressed by the market-place rather than by the scientific advisory system.

17. Practicalities—The system is not, therefore, in a position to consider the practicalities of controlling the technology—and there is no other mechanism in place that can do so. For example, the problem of ensuring traceability of GM ingredients throughout the food chain was not anticipated as it did not fall within the remit of any of the advisory committees, although traceability is now recognised as essential for ensuring food safety following the BSE crisis.

18. Global considerations—GM foods are being developed globally, but this is not adequately reflected in the way that they are approved. There are insufficient controls at international level covering how they are approved and monitored. Different scientific committees around the world have also reached different conclusions on the same products, based on the same evidence, but based on different judgements about whether or not a risk is acceptable, as discussed in paragraph 15. As we now operate in a more liberalised trading environment it is important that international controls over the technology are agreed.

International dimension

19. The concerns set out above in relation to the UK scientific advisory system apply equally at European and international level. Although the Inquiry is focusing mainly on the UK scientific advisory system we would be happy to provide the Committee with a further memorandum detailing our concerns in this area. In particular, there has been a failure to acknowledge the importance of consumer input at all into the EU committees. Although they now sit within DGXXIV which has responsibility for consumer policy and consumer health, no consumer representatives have been appointed and they do not operate openly and transparently. The same concerns apply to the committees that advise the Codex Alimentarius Commission. These are both discussed in some depth in *"Confronting Risk"*. Given the fact that food legislation is increasingly decided at EU level and that Codex standards are now used as the basis for settling disputes by the World Trade Organisation, it is important to ensure that the scientific advice provided at this level is also of a high quality.

An Overarching Body

20. We consider that one step towards improving the current system is to create an overaching advisory committee which could consider broader aspects of the technology. This would be able to address the gaps within the current system—where issues can fall between the narrow remits of the existing advisory committees. It would be able to co-ordinate the work of the committees and ensure a joined-up approach to developments from experimental stage through until the final product reaches the consumer. The remit of such a committee would therefore need to include the long-term safety and environmental implications of genetic modification, as well as ethical implications and practical aspects of its use. The committee would need to be pro-active and anticipate future developments. It would need to have a multi-disciplinary membership, and effective consumer representation and representation by other relevant stakeholders.

The Government as an "Intelligent Customer" for the Advice it Receives

21. The role of the scientists and of government have often been blurred in the way that GM foods have been handled. This is typical of the approach that has been taken more generally to food risks. Acting on the advice of the scientists has often been presented as the only justification considered necessary for decision-makers. The risk assessment has tended to dictate a decision, rather than inform it. Even if this is not the case in reality—and other factors have influenced the Government's decision—the lack of openness has meant that it is often difficult to see the political and economic factors that may have also determined policy.

22. But, as already emphasised, genetic modification raises many issues that go beyond scientific factors. When deciding on the action that is needed, the Government needs to consider a wide range of other factors, including the need to take a precautionary approach in view of the irreversible nature of the technology. It is the Government that has responsibility for weighing up whether or not the benefits to consumers outweigh any long-term implications for health or for the environment and vice versa. But there has been a lack of clarity about who makes these decisions, and responsibility has fallen to the scientists.

23. There has also been a breakdown in the risk communication role that government should play. Scientific advice needs to be communicated clearly to government and the public setting out any remaining uncertainties and any judgements that were made to arrive at the relevant committee's conclusions. However, the Government also has a crucial role in explaining the risks posed by the technology to the public. In recent weeks we have seen a return to traditional blanket reassurances about safety when faced with concern about the long-term safety of GM foods, instead of acknowledging where the uncertainties lie and how the Government intends to address them. This has resulted in a breakdown in trust.

24. Risk communication is viewed in its very narrowest sense in relation to GM foods. The need for an effective dialogue with consumers has not been accepted. Although a suggestion was made by government that a stakeholder forum would be established to feed into government policy on GM foods, this has not been established. The lack of any dialogue with the public has been reflected in government policy, where there has been a failure to acknowledge consumer concerns sufficiently early.

Experience of Advising the Government on these Matters

25. CA has made its concerns about the technology clear to government on many occasions. The concerns outlined above were raised in our policy report "*Gene Cuisine*" and more generally in relation to food policy in "*Confronting Risk—a new approach to food safety.*" Although we have had opportunities to discuss these issues with Ministers, the approach taken to this issue has changed very little and our concerns remain.

Interaction With or Participation in the Advisory System

26. One of the main flaws with the current approach is that it fails to acknowledge the need to consider consumer concerns throughout the process. There has therefore been a mis-match between the way that scientists' and decision-makers perceive the technology and the way that consumers do.

27. A clear example of this is the approach that has been taken to labelling of GM foods. When the FAC considered labelling in 1994 they considered that labelling of GM foods was only required under very specific narrow circumstances, based on the recommendations of the Polkinghorne Committee: if the product contained a copy gene from a human, from an animal raising religious concerns or if an animal gene had been copied into a plant. However, our own research has repeatedly shown that consumers want all genetically modified foods and ingredients to be labelled. But there was still a failure to reflect these concerns within the EU novel foods regulation and within the Government's subsequent negotiating position during the UK Presidency when the regulation on GM soya and maize was decided, exempting many GM ingredients.

28. Consumer representation and public participation within decision-making can bring several benefits:

- it enables public's perceptions of risk to be understood and acknowledged;
- it can make the process more open and transparent;
- it enables a sharing of new ideas and approaches;
- it can enable practical issues to be considered which may escape the scientific expertise on the panel;
- it can improve the quality and credibility of decisions as they are subjected to public scrutiny;
- it helps to ensure that there is public confidence in the system and its decisons.

29. At a more fundamental level, the consumer representative can ask the questions that consumers want answering. This can help to ensure that consumers' concerns are addressed, but also that the risks are communicated in a way that consumers can understand and can act upon. It can also bridge gaps between the different disciplines that sit on the committee.

30. As highlighted above, decisions about genetically modified foods often have to be made when there is a great deal of uncertainty. In such situations, the scientific evidence may not be available upon which to base a committee's deliberations. Judgements therefore have to be made. The public therefore has as much right to be involved in these deliberations. Their views are just as relevant as those of the scientists.

31. So far, we have focused on consumer representation on the scientific committees, ie during the risk assessment. However, it is important that there is an on-going dialogue with consumers throughout the whole decision making process. A much broader approach therefore needs to be taken to risk communication—it needs to be seen as a two-way process, helping to ensure that the public's views about risks feed into the process, and that decision-makers and scientists keep the public well informed of any developments.

32. Public participation therefore has to begin even before the risk assessment—when decisions are made about what research is needed, and what issues need to be addressed by the scientific committees. In the case

of the over-arching committee mentioned above, this would mean finding out what issues concern all relevant stakeholders and need to be taken on board within the remit and subsequent deliberations of the committee.

33. Unfortunately, there remains a lack of willingness to experiment with methods of public participation. Appendix 5 of our report *"Confronting Risk"* gives an overview of the methods of public participation that are now available and which are relevant to this issue.

Conclusion

34. A new approach to assessing risks from GM food is required if consumers are to have confidence in the regulatory framework. Such an approach needs to:

- — ensure greater co-ordination of GM developments from the research stage through until a product is marketed—an overarching committee would help to achieve this;
- — acknowledge the uncertainties inherent in any analysis of the safety of GM foods;
- — consider the broader implications of GM foods, such as ethical and environmental concerns and the impact on agricultural practices and move away from a case-by-case, product-by-product approach;
- — anticipate future developments, consider their implications and acceptability, and how they can be controlled—before products reach the shelves;
- — take a precautionary approach where there is uncertainty, and therefore;
- — ensure effective public participation throughout the process, including effective consumer representation on the advisory committees; and
- — ensure that decisions are made openly and that committees function transparently—the basis of the committee's conclusions including any uncertainties that remain, and any assumptions that have been made should be clear.

March 1999

APPENDIX 23

Memorandum submitted by the Country Landowner's Association

The Country Landowner's Association (CLA) represents the interests of some 50,000 landowning members in England and Wales whose total acreage amounts to some five million hectares. Our members' interests extend beyond agriculture into the rural economy at large and as such, many will be affected by the introduction of genetically modified crops, from differing standpoints.

CLA policy on GMOs is mainly encapsulated in two recent CLA briefing notes which are attached at Annexes A and B.[20]

We respond to the inquiry in the order of questions which the Committee are to consider.

The Adequacy and Quality of Scientific Advice at Present

1. We understand that the Regulatory system for the approval of GM crops is thorough and comprehensive. However, we are concerned the system may not be equipped to answer the questions raised as a result of the rapid development of the science over the past decade. For example there is concern about the relevance today of the principle of "Substantial Equivalence" which underpins the EU/UK Approvals Process and WTO rules on the trading of GM crops. Substantial Equivalence assumes that GM products of the same chemical composition as their non-GM counterparts are similar and hence obviated of the need to undergo general toxicity testing. However, only such testing would pick up, for example, knowledge about the effects that the process of genetic modification may confer upon the host DNA. For example the "process" of genetic modification or the use of secondary genes to switch engineered traits "on and off" may themselves bring about the creation of new pathogens or viruses.

2. The widescale and relatively speedy development of this technology make quantifying its potential costs difficult. The BSE crisis has had a severe economic effect on many of the CLA's members, even though the exact "cause" of BSE remains unproven. As such, the Government needs to consider carefully how to balance decision-making and Regulation on the basis of what is "currently" scientifically known about the application of this technology with the Precautionary Principle, which goes further, in evaluating possible future risk. This is especially important where the short-term benefits of agricultural biotechnology could be offset by long-term health and ecological costs which we have no way of calculating at present.

3. Roy King, member of the Governments own "People's Panel" on biotechnology illustrates the problem of having a "mechanistic" (or linear) view of natural systems when he says "scientists who normally deal in

[20] Not printed.

the linear measurements, put hypotheses based on normal mathematical or statistical measurements. If they then seek to use such linear techniques to justify quantum systems, gross errors will be made . . ." "the two systems (linear and quantum) are fundamentally different". The introduction of GM crops inevitably raises questions which bear closer relationship to quantum systems, particularly as new and multiple traits are continually introduced to the biology of our environment and food supply.

4. There is a belief that ethical assessment is increasingly losing out to scientific analysis and though the disciplines are both different, each is important in its own right. The CLA believes there is need for a greater interlinkage between the two. The changes wrought by genetic modification, which have mainly taken place in the past decade and which will undoubtedly increase in number and complexity in the future, are a radical departure from natural evolutionary processes and the specialised and selective breeding that has occurred within agriculture. They enable exchanges of genetic material to occur between different Kingdoms where once the species barrier acted as a brake. Such departures from the evolutionary process call for a greater degree of caution to enable time for a proper scientific assessment of the risks as well as the incorporation of ethical issues into the debate. Wider ethical issues may include, for example, the right for a country to say "no" to the importation of GMOs[21] and the right of consumers to be properly informed where foods already on the shelves contain genetically modified ingredients.

5. Clearly, public disquiet about the issue of genetically modified food, and the Government's handling of it, is reflected in the opinion polls. In particular, the difficulty in properly segregating GM from non-GM, particularly in imported crops, has led the public to believe that GM crops are being forced upon them, allowing no choice. As such, the public are left with the impression that there are no controls in place.

The role and framework of advisory committees

6. In relation to the Government's organisation of advisory committees, a clearer distinction needs to be made in the distinction between applications of biotechnology in medicine and in agriculture. This would make the process of authorising developments in biotechnology appear less opaque to the public and, in the case of food biotechnology, would eneable public values to be more accurately reflected in the shape of demand for GM food products.

7. The CLA is greatly concerned that major gaps exist in terms of the issues not dealt with by the existing advisory committees. These include:

(a) *The political and commercial effects of GM are not covered by the Committees*

None of the Committees has a remit to look at the policital and commercial effects of GM. Yet there appears to be both political and commercial pressure being exerted in order to get GM products onto the market. There is a need for a Committee, run along the lines of Lord Nolan's, to ensure that such pressure is not brought to bear.

(b) *Liability*

The question of "who will be liable" for "what" damage arising from GM crops is not one covered by the Committees.

For example the costs of recall and cleanup and to identify "who" is to pay for what. The case, highlighted in the press on 4 February, of the organic tortilla chops which had to be recalled following the discovery that GM maize had cross-pollinated with the organic maize illustrates the dilemma.

The CLA is concerned about the potential liability for the landowner or farmer associated with possible "harm" (eg health or environmental) arising from GM products. There needs to be a clause in both the EU's Product Liability Directive and the Directive 90/220 (governing the authorisation and marketing of GMOs) which enables liability to be passed further up the chain, to the innovators of GM seeds and inputs, rather than stopping at the farmer.

(c) *Labelling and segregation of GM products*

The CLA has always advocated the segregation and labelling of GM crops throughout the food chain (from seed to shelf) in order that both farmers and consumers have a degree of choice in opting for using GM products or not. Significantly, there is a concern with the current arrangements for labelling of GM products, particularly as so much food on supermarket shelves contains soya by-products.

Without the proper segregation of GM from conventional crops it will become impossible to label products as "GM-free" and to provide the public with a choice. The possibility of animal feeds being unlabelled and containing GM by-products will also undermine public confidence.

[21] As highlighted under our general comments the principle of *Substantial Equivalence* means that a country is obliged (under WTO and EU rules—to import products which are *"substantially equivalent"* (or chemically similar) to non-GM varieties, despite being produced by different techniques.

(d) *The Framework is not equipped to deal with the issue of the cross contamination of organic crops*

Some of the CLA's members are organic farmers. The recent Court of Appeal Case *Regina v* Secretary of State for the Environment and MAFF ex parte Watson last year drew attention to the land management implications of GM crops. This is not least because the integrity of crop certification/assurance contracts (such as the Soil Association certification in that case) may be jeopardised by the possibility of cross contamination. Also the organic tortilla chips which had to be recalled at great expense following the discovery of GM DNA (arising from cross contamination with neighbouring maize) has implications for both on and off farm insurance claims. Such a state of affairs could result in legal claims or disputes between neighbours or landlord and tenant.

8. We welcome the decision to have more representation on the ACRE Committee by ecologists (when ACRE is re-shuffled in April). Until now it appears that ACRE has, despite its name, not concerned itself with the "knock-on" and "collective" effects of GM crops in the wider biological environment. Neither has it had a remit to assess how changes in agricultural practice arising from adoption of GM techniques (eg the increased usage of broad spectrum herbicides) may impact upon biodiversity.

9. The CLA believes that the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC), which will self regulate the management of GM crops on the farm and in processing, must report in a formalised way to the relevant Government Committees.

10. The CLA believes that the potentially far reaching implications of GM crops call for "more-than" an industry led approach to their management. As such, the CLA did not endorse the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC) code because it believed it to be too "supply chain" (eg "plant breeders") orientated, whilst the CLA felt the longer term implications of GM called for "more-than" an industry led approach.

11. The SCIMAC code of practice for the management of GMHT crops still has many issues to resolve; not least those related to effective segregation, compliance, sanctions and independent audit. The CLA hopes that the Government will consult more widely on these issues before giving the industry the "go-ahead" to regulate itself. This will be of paramount importance if the SCIMAC Code is to gain credibility with the public.

12. The Government's reasoning for "self regulation" (at the time of the Meacher/Rooker statement on measures for GM in agriculture in October) was that the introduction of commercially grown GM crops could occur more quickly than if revisions to the EU Directive 90/220 had to be waited for. However revisions to Directive 90/220 are expected to be completed this summer, rather than in several years as the Government had expected.

THE ABILITY OF THE CURRENT SYSTEM TO RESPOND TO RAPID SCIENTIFIC DEVELOPMENTS

13. There is concern about the ability of scientists to cope both technically and administratively with the demands made on them by the food safety system generally and the introduction of genetically modified foods/crops in particular. The remarks made by Professor James and Dr Chesson, as published in the House of Lords Report "EC Regulation of genetic modification in agriculture" (December 1998), indicate that the pressure to proceed with food safety decisions often seems to be driven more by trade than by scientific considerations. Though some of the remarks relate to the European Committees, current developments in GM may make some of them equally applicable to the UK.

14. The CLA recognises that the current regulatory structures may be subject to tremendous pressure in future, as a result of the enormous number of GM crops now in the research pipeline. It should be remembered that we are talking about attempting to assess hundreds of new organisms, rather than just one as in the case of BSE.

15. There is also concern about trade considerations (especially trade war) driving the food safety process. The Government needs to balance the introduction of GM crops with many interests (consumers, environmental groups, food producers, farmers and landowners) rather than solely capitulating to the impetus for free trade in GM products, pushed by multi-national conglomerates.

TO WHAT EXTENT THERE IS VALUE IN THE PROPOSAL FOR AN OVER-ARCHING BODY TO ADVISE ON AND OVERSEE ALL GENETICALLY MODIFIED FOOD ISSUES

16. The CLA welcomes the Government's initiative in setting up an environmental stakeholder forum because currently stakeholders are not given an opportunity to influence the process of approving GM products. However, rather than running "in-parallel" to the Advisory Committee on Releases to the Environment (ACRE) Committee, this forum should feed into the approvals process as an "over-arching" committee. We await details on "how" stakeholders will be selected and whether, if at all, their comment will have a bearing on the Approvals process for the commercial release of GM crops.

17. The forum should have broad representation and both the forum and the ACRE Committee should include expertise on land management, ecological, biodiversity and legal issues.

18. The stakeholder forum should report to the Head of the Cabinet Committee on genetic engineering. Its advice should be made public.

THE CAPACITY OF GOVERNMENT TO BE AN "INTELLIGENT CUSTOMER" FOR THE ADVICE IT RECEIVES

19. Government is more likely to be an "intelligent customer" for the advice it receives if:

(a) the advice in question is made more transparent to the public at large;

(b) mechanisms which enable people's values to be articulated are built into the regulatory structure at key stage. For example, not just "Stakeholder fora" but other structures, such as those mentioned by the Royal Commission on Environmental Pollution in its response to the Cabinet Committee's consultation in February.

15 March 1999

APPENDIX 24

Memorandum submitted by Professor Derek Burke, Chairman of the Advisory Committee on Novel Foods and Processes, 1989–97

1. THE ADEQUACY AND QUALITY OF SCIENTIFIC ADVICE AT PRESENT

1.1 The current UK system uses a network of Advisory Committees, composed of senior academics from Universities and Research Institutes, serviced by civil servants, and advising Ministers, again through civil servants. I know the system well—as Chairman of the ACNFP from 1987–97, and a member of the ACGM from 1987–95. I have also attended meetings of other Advisory Committees from time to time.

1.2 The system has considerable strengths, viz.:

— It is truly independent, since members are not government employees (as they are elsewhere in the EU and in the US), and in my nine years I never had any political pressure exerted on me by politicians, although I was occasionally lobbied by companies. Both ACNFP and ACGM quite frequently did not follow the advice put to it by civil servants, and it was made quite clear to me during the first crisis over GM soya in December 1996, that I could speak to the media, and frequently did, without clearing it with Ministers. Members are appointed by Ministers, as is wholly appropriate, and again I have not seen that power misused.

— The Committees are expert; for the very best people in the UK have given huge amounts of time to the Advisory system for little or no payment. There is substantial interaction between the experts too; frequently, discussion between experts in the Committee uncovered issues that no one person could have been aware of. The Committees function, in my view, much better than the practice common elsewhere of using scientifically qualified civil servants, who are not independent. However, payment is now an issue, and partly because of the considerable work load, and partly because Universities are increasingly reluctant to release staff without compensation, the whole issue of personal and institutional payment needs urgent attention.

— Some Advisory Committees have had user representation for many years. ACGM was, from its inception, a tripartite committee with representatives from employees, experts and users (the latter nominated by the Trade Unions). This has worked well. A consumer representative (Mrs H Millar) and an ethical advisor (Revd J C Polkinghorne FRS) were added to the ACNFP on 01.12.91 as a direct result of a workshop held on 09.09.90, whose aim was to make a series of proposals to increase transparency since, as I said on that occasion: "the Committee believed that if there was a failure to explain the basis for the clearances given, it would not carry the confidence of the general public or opinion formers" (ACNFP Annual Report, 1990). This initiative, and others undertaken at the same time, have now become established procedures. The presence of these two members of the Committee had had several beneficial effects. The first was that there was a change in the way that the scientists approached issues coming to the Committees: everyone became much more aware of consumer perceptions and built them into the discussion from the beginning. We never had a situation where the consumer representative was at odds with the rest of the Committee, and I always ensured that she was content before a decision was finalised. I have come firmly to the view that consumer issues and technical issues are best considered side by side; and that the previous practice of first sorting out the science, and then considering the consumer issues is no longer adequate. The presence of the consumer representative had the additional advantage that when she was approached by the media, which occurred frequently, she could witness to the robustness and independence of the Committee. The presence of the ethical advisor was valuable on a number of occasions; not to tell us what was right or wrong, but to warn us that in his view there was an ethical issue that called for attention. A discussion, initiated by a request to the Committee to allow sheepmeat containing either a partial or a complete single human gene to enter the food chain, led

directly to the formation of the so-called "Polkinghorne Committee", of which I was a member, and which was, I believe, the first group to explore such an issue through a process of consultation, and to identify the problems associated with segregation and labelling of GM foods. (Report of the Committee on the Ethics of Genetic Modification and Food Use, HMSO 1993).

1.3 The current system also has a number of disadvantages:

— The case by case approach has proved inadequate as the number of approvals have grown. This approach was quite satisfactory for a number of years; and over time, the "principled pragmatism" approach of the Advisory Committees has developed into a more systematic approach, with the build up of case law and the development of "decision trees" by the ACNFP. However, the cumulative implications of successive decisions have not been considered—it was not in the terms of reference of either ACNFP of ACRE—and with the growing number of approvals, such a mechanism is now necessary. I consider that this is a more serious problem in the environmental area—where, for example, two farmers may both be growing different herbicide resistant rape varieties without considering their interaction—than in the health area, but is one that is straightforward to solve by appropriate widening of the terms of reference.

— Issues falling between Committees. There has always been cross representation between Committees, for example between ACGM, ACNFP, ACRE and COT, and few problems which could not be resolved by meetings between the two Committees, or by appropriate sub-groups. For example, the differing advice offered to Ministers by ACNFP and ACRE over the Ciba-Geigy Bt corn was resolved by such a meeting, chaired by a senior civil servant. However such resolutions depend on the acuity of the civil servants or Committee members involved, and the present situation is not disaster-proof. There was, for example, no meeting of Committee Chairs in my time, apart from a few ad hoc meetings convened by the DoH to consider consumer representation and general issues of risk perception. I was in informal contact with other Chairs by phone, but in retrospect regular meetings to discuss policy and problems would have been very useful, although I understand that at least one such meeting has now taken place.

— Different perceptions of risk. In the 10 years since I started with ACNFP our understanding of the ways in which risk is assessed differently by technologists and the general public has grown greatly, largely due to the work of a number of social scientists, and now picked up by the Risk Communication Unit in the DoH. We have found that despite the presence of our consumer representative and ethical advisor, the public still have lost a lot of confidence in what they hear from regulators. There are several reasons for this loss of consumer confidence. First, scientists, and the expert approval processes, are no longer trusted as they once were. The BSE epidemic has of course been a major factor here. Second, I think the public is largely unaware of the development of careful scientific methods of assessing risk, such as the use of hazard analysis, to come much closer to an "objective" evaluation of risk. But it is also true that we find great difficulty in explaining, and the public in understanding, what is meant by different degrees of risk. Third, the public finds it difficult to know how seriously to take the points put by the many single-issue pressure groups, and fourth, risks are assessed differently according to the context. We will accept quite high risks when we are seriously ill, but will not tolerate much risk at all with food. It is essential that urgent steps be taken to regain public confidence in the regulatory system, and some measures are already in hand. The greatly increased transparency of the regulatory process and the coming Food Standards Agency will all help, but I believe that we now need to work out a new approach to the regulation of new technologies which makes possible their introduction while maintaining the confidence of the public. We don't want another food irradiation fiasco!

— Ethical Issues. These are currently handled in a very variable fashion, and I believe that the ACNFP is the only Advisory Committee that has an ethical adviser as a member. I recommend that all Advisory Committees should have such an adviser, who might well be the same person for several committees to maintain a consistent approach. However, as I have said above, the function of the ethical adviser should be to alert the Committee to such ethical issues, while the full debate should take place elsewhere, I suggest in the over-arching body.

2. The Ability of the System to Respond to Rapid Scientific Developments

My experience is that this is very high, provided that great care is taken to ensure that the members are (i) at the cutting edge in their field (ii) willing and able to read the papers for the meetings (often very bulky), and attend all the meetings, (iii) willing to speak concisely, argue fluently but fairly, and (iv) be completely discrete. In addition the Chair of the Committee must be able to handle an increasingly hostile media and carry a heavy work load. ACNFP took about two days a week of my time in the last two years of my service, although I was retired by this time. I believe that it is getting increasingly difficult to persuade the very best people to do all this work for effectively no payment or public acknowledgement, with a loss to their scientific career prospects purely out of a spirit of public service. I do not think that the current system is stable.

3. The Need for a New Overarching Body

4.1 The Royal Society in the Report of a Working Party (of which I was a member) entitled "Genetically Modified Plants for Food Use" urged "Government to establish an independent overarching body to span departmental responsibilities, monitor the enforcement of existing or future regulations and strengthen the guidelines to growers of such crops. . . The body should also review and monitor the membership of advisory committees and regulatory bodies." A similar recommendation was made by the House of Lords in its Report "EC Regulation of Genetic Modification in Agriculture". The first of these objectives should now be the responsibility of the new cross-Whitehall body, but it will not be able to deal with the others. The overarching body should in my view have a triparite membership; with representatives of scientists, producers and retailers, and consumers, including ethical advisers, in roughly equal proportions. It should report to the cross-Whitehall body, and should be expected to advise on both current and potential issues on a case by case basis, rather as the HFEM does. It should be chaired by an independent, high profile public figure, who will have to act as its public face, especially to the media.

4.2 The Government has also recently raised the possibility of an environmental stakeholders forum, and although few details are available, I do not find this proposal attractive. Primarily, I think it is a mistake to separate environmental issues from scientific and commercial issues; for these should be debated together, otherwise the committee will be no more than an environmental lobby and will soon be marginalised. But I have a number of other concerns about this proposal. Membership issues will be crucial. Will it include farmers, plant breeders, the seed trade and biotechnology companies, as SCIMAC (Supply Chain Initiative on Modified Agricultural Crops) does, in addition to such groups as English Nature and RSPB? Will it also include such groups as Greenpeace and Friends of the Earth? If so, how will agreement ever be reached? Then what are its powers? If it is purely advisory, will it become a mere talk shop? To whom does it report? Directly to the Minister? If so, who will resolve the inevitable differences that arise from the Advisory Committee system and the stakeholders forum? How will these two groups communicate? For if they do not, they could make decisions on different bases. All these considerations, together with the need for an open, transparent system argue, I believe, for the Royal Society proposal of a single over-arching regulatory body, which would advise and report directly to Ministers. In this case there would be no need for an environmental stakeholders forum.

18 March 1999

APPENDIX 25

Memorandum submitted by the UK Life Sciences Committee

Introduction

The UK Life Sciences Committee (UKLSC) comprises 13 learned societies in the molecular, cellular, and physiological life sciences and represents some 30,000 biological scientists in universities, government and charitable research establishments, and industry. The memorandum below was compiled in consultation with all member societies.

At the outset of this response, UKLSC expresses its support for the arguments presented by the Royal Society in its paper "Genetically modified plants for food use" and the main recommendations for improving the regulatory framework included in the later response "Regulation of biotechnology in the UK". Those recommendations were drawn up with particular reference to GM crops. UKLSC also endorses the principles set out by the Government Chief Scientific Adviser in his 1997 paper "The use of scientific advice in policy-making". At issue, however, is the extent to which the principles are achieved by Government Departments.

The Adequacy and Quality of Scientific Advice at Present

1. Britain's academic excellence in the molecular life sciences is recognised internationally. The Government wisely includes independent scientists among members of the Advisory Committee on Genetic Modification (ACGM), the Advisory Committee on Releases to the Environment (ACRE) and the Advisory Committee on Novel Foods and Processes (ACNFP), all of which provide advice on aspects of GM foods. In addition, an expert panel of the Royal Society drew attention in the paper above to a number of concerns about GM crops for food, before these were recognised and later blown up by the media. The problem was not inadequate or poor quality scientific advice *PER SE*.

2. The perceived government delay in responding to the Royal Society paper, and in publishing a report from ACRE that was expected to highlight environmental concerns, allowed the media to accuse the Government of seeking to conceal information. This suggests that there is still a need for greater government openness in soliciting and interpreting advice, particularly where the understanding of risk is a key factor.

3. Opinion polls show that the general public has more confidence in dispassionate scientific advice given by independent university scientists than in that given by government or industry. In the recent GM foods controversy sections of biotech industry were considered to have too much influence over government, and concerns were expressed about the real independence from agri-business, or a commercial interest in the exploitation of genetics, of some academic members of Advisory panels. Whilst the scientific community

applauds the Government's enthusiasm for biotechnology, and its drive for information and skills transfer between academia and industry, it considers it essential that adequate public funding is available to underpin commercially independent research in universities.

4. UKLSC is concerned that the irresponsible coverage by some sections of the media will have lasting consequences on scientists' willingness to enter the public arena, which may make it more difficult in future for the Government to secure independent scientific advice.

The Role and Framework of Advisory Committees

1. UKLSC supports the views of the Royal Society on gaps in coverage, the existence of overlap, how the current system could be restructured, and the need for an overarching body. The current use of specialised Advisory Committees would be more efficiently co-ordinated if the Chairs of these Committees had an official forum in which to discuss concerns raised by their committees. There has been concern that consumer and environmental interests are under-represented on the Advisory Committees, and that this led to ecological/environmental issues not being adequately considered. It is understood that the Government now plans to increase the number of environmental advisors on ACRE.

The Ability of the Current System to Respond to Rapid Scientific Developments

1. In view of the pace of change in the molecular life sciences the Government should not just rely on its Advisory Committees, but should interface more broadly with scientists so that advice can be obtained quickly as issues emerge. UKLSC is in a position to identify sources of expertise on particular issues among its members and would be pleased to be consulted on issues in the cellular, molecular and physiological life sciences. It would endeavour to give a prompt response.

2. UKLSC also supports the Royal Society recommendation that increased flexibility and faster adaptation could be achieved if Advisory Committees co-opted members on an *ad hoc* basis to provide advice on particular issues, or set up *ad hoc* working groups to consider specific issues of concern. Again, UKLSC would be happy to recommend suitable scientists.

The Proposal for an Overarching Body to Advise on and Oversee all GM Food Issues

1. An overarching body is required for the following purposes:

   (1) to aid co-ordination of the actions of the different Advisory Committees, as outlined above;

   (2) to ensure that wider issues of the impact of GM technology on agriculture and the environment are adequately assessed, as recommended by the Royal Society;

   (3) to develop ways in which public values can be taken into account in decisions on the introduction of GM technology. Surveys have shown that science-based approaches alone cannot be relied upon to reach socially acceptable decisions on issues involving the assessment of risk;

   (4) to anticipate, identify to the Government, likely problems in public acceptance. One factor undermining public confidence in GM technology is the lack of understanding of the nature of scientific evidence and of risk. The Government needs to consider how it can best inform the public on these issues. The Government currently favours focus groups and consultations to determine public views on particular issues. It should perhaps do more to shape those views by organising more consensus conferences to draw in stakeholders, or by commissioning a respected body such as the Royal Society to produce reports on sensitive issues. The US National Academy appears to be successful in capturing a consensus view by careful appointment of chairs and committee members so as to ensure that all interests are represented, and by non-dogmatists. Its reports have been influential in drawing a line under controversial issues. This may be a good model;

   (5) to provide strategic advice on GM issues to the Government that will inform policy making in the longer term. The Government should not use scientific advice merely in response to individual short-term priority issues, or for "fire-fighting".

The Capacity of Government to be an "Intelligent Customer" for the Advice it Receives

1. Communication and coordination of scientific advice between government departments appeared unsatisfactory in the recent controversy in that the Department of the Environment and the Department of Trade and Industry were perceived to hold different views on safety issues, and consequently on what would be an acceptable pace of commercial introduction of new GM crops. The earlier Royal Society response made a series of recommendations for improving communication. The effect of the poor communication is that the Government has had to backtrack, appear secretive in its decision-making, and is seen to be responding to events rather than shaping them. Government also appeared not to appreciate sufficiently the importance in shaping public opinion of factors such as a suspicion about the motives of large agri-business, the threat to freedom of choice, and the background public mistrust arising from earlier BSE and E coli scares.

2. Although ministers in the present Government are more accessible to scientists than their predecessors, much contact is with officials, who may not have had scientific training. As was pointed out in our earlier submission to the Science and Technology Committee on Government use of scientific advice, UKLSC has been advised that the translation of scientific advice by non-scientific officials can reduce its effectiveness, or distort it.

19 March 1999

APPENDIX 26

Memorandum submitted by Office of Science and Technology

INTRODUCTION

1. This memorandum responds to the request of the Science and Technology Committee of the House of Commons to the Office of Science and Technology (OST) to submit a Memorandum to its Inquiry into the Scientific Advisory System: Genetically Modified (GM) Foods.

2. OST has no direct role in the regulation or development of policy on genetically modified food. These are matters primarily for the Ministry of Agriculture, Fisheries and Food (MAFF) and the Department of Health (in consultation with The Scottish Office, Welsh Office and Northern Ireland Office). This memorandum does not address the specific questions raised by the Committee, which would be more appropriate for those departments. Instead it sets out:

OST's general responsibilities for coordinating scientific advice on genetically modified foods, and the Chief Scientific Adviser's (CSA) personal role, in the context of the Office's wider responsibilities in relation to scientific advice to Ministers. These are set out more fully in the memorandum submitted by OST on 17 June 1998 in response to the Committee's call for evidence to their Inquiry into the Scientific Advisory Systems. Among other things, this sets out: the means by which Government uses scientific advice to inform decision-making and policy development, and the quality of the advice obtained; the ways in which Government approaches establishing confidence in science and its use in policy making; and the organisation of scientific advice to Government. An update of that memorandum will be submitted separately by OST by Easter in response to the Committee's request.

— OST's responsibility for support to the Ministerial Committee on Biotechnology (MISC 6), and for coordination at official level through the Interdepartmental Group on Genetic Modification Technology (IGGMOT);

— Activities currently underway in which OST is involved, which are directly relevant to the Committee's Inquiry, including a review of the framework for regulation of biotechnology commissioned by MISC 6 and a public consultation on the biosciences;

— the ways in which programmes for which OST is responsible touch on genetically modified foods.

OST ROLE IN GM FOODS POLICY

3. OST's objective in respect of GM foods, as with other science and technology issues, is to ensure that other Government Departments' decisions are based on the best scientific advice available. OST's earlier memorandum to the Committee[22] described its role within Government on policy issues with a high science and technology content; and sets out how it is organised to achieve its objectives. The Chief Scientific Adviser, Sir Robert May, is responsible for advising the Prime Minister, the Cabinet and the Secretary of State for Trade & Industry on science and technology issues. As Head of OST, he is also responsible for its transdepartmental functions. An important part of this role is to ensure that important science and technology issues that cut across Departmental boundaries are effectively handled. In doing so, the OST acts as adviser and facilitator, for example:

— helping to flag up strategic issues from a broader perspective than that of any single Department;

— working with other Departments to identify good practice in handling of S&T issues;

— contributing, from its central position, to advice to Ministers collectively, and to the Prime Minister, on major policy issues;

— developing and promulgating guidance to departments on the use of scientific advice in policy making. The Chief Scientific Adviser's guidelines, published in March 1997, were developed in consultation with departmental Chief Scientists, the Research Councils, the Royal Society and the Council for Science and Technology. They set out key principles for departments to apply to the use and presentation of scientific advice in carrying out their work.

[22] House of Commons Science and Technology Committee Inquiry into the Scientific Advisory System: Memorandum submitted by the Office of Science and Technology 17 June 1998.

4. In carrying out these functions, OST has a strong interest in the development of government policy on biotechnology, including genetic modification. Many Government departments have responsibilities in this area of policy. OST's role is to encourage effective coordination, and to ensure that the Government is receiving the best scientific advice. As part of this work, OST provides support jointly within the Cabinet Office for the Ministerial Group on Biotechnology and Genetic Modification (MISC 6) announced by the Prime Minister on 21 October 1998[23] which takes an overview of all biotechnology issues. The terms of reference of the Committee are: "to consider issues relating to biotechnology, in particular those arising from genetic modification".

5. OST also chairs and provides the secretariat for IGGMOT, established in 1993 to provide a forum within Government for debate of genetic modification (GM) policy, both domestic and international, at official level across Government. Individual departments maintain control of GM policy at the departmental level, with IGGMOT, providing co-ordination and promoting exchange of information. It also seeks to identify emerging activities within the field of genetic modification. The establishment of the Ministerial Group on Biotechnology and Genetic Modification has not changed the role of IGGMOT which continues to act as a mechanism for official level co-ordination of policy and exchange of information on genetic modification technology between Government departments.

Review of Framework for Overseeing Developments in Biotechnology

6. One of the first decisions made by the Ministerial Group was to initiate a thorough review of the framework for provision of advice to Government on developments in biotechnology. The aim is to ensure that the Government has in place a system that provides sound advice and proportionate regulation and is at the same time as simple and transparent as possible; that has the flexibility to respond to the fast moving developments in the technology and to public concerns; and that commands the respect of users and the public. The Minister for the Cabinet Office announced the Review on 17 December 1998[24].

7. The Review is being carried out by officials from the Cabinet Office and the OST on behalf of the Ministerial Group. Officials have sought the views of the existing regulatory and advisory bodies themselves, and of outside bodies with an interest in this area. The views of the public have also been welcomed. Over 130 responses have been received as at end of February.

8. Ministers will consider the outcome of this review later in the spring, in parallel with the emerging conclusions of the Government's public consultation on developments in the biosciences, which is being run by OST.

Public Consultation on Developments in the Biosciences

9. John Battle MP, then Science Minister, announced the public consultation in July 1998. The objective is to investigate public attitudes to the implications of recent developments in the biosciences including GM foods. The project is exploring the public's understanding of the scientific developments and their potential application. It is seeking the public's views on the issues arising out of the scientific developments, the adequacy of the existing regulatory framework and on sources of information or the lack of them.

10. Lord Sainsbury, the Minister for Science is leading the consultation, assisted by an independent advisory group: a list of membership is attached. Ministers held meetings with a wider group of stakeholders in March and December 1998. Minutes of these meetings and those of the Advisory Group are publicly available. OST have engaged MORI to undertake the consultation. The first stage involved six two-day workshops involving 20–25 people; the second stage now underway is a survey of 1,000 members of the People's Panel, constituting a representative sample of the UK population.

Papers by the Chief Scientific Advisor

11. The Chief Scientific Advisor's paper "Genetically Modified Foods: Facts, Worries, Policies and Public Confidence" was circulated to all MPs together with other factual material on GM foods on 18 February, under cover of a letter from five Secretaries of State. He has also been commissioned by Ministers to write a paper, jointly with the Chief Medical Officer, on the public health implications of genetically modified foods.

Other OST Activities

12. Through the science budget, OST funds Research Councils which in turn fund research on genetically modified food. However, under the Haldane principle, OST has no involvement in decisions on what research is funded.

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[23] *Hansard* 21 October 1998: Col 1134.
[24] *Hansard* 17 December.

13. OST also runs the Foresight programme. Foresight groups, comprising senior people from the business and science communities have in the past commented on the opportunities for GM technology to benefit the UK, and on the need for proper safeguards.

14. Some GM research is carried out within LINK programmes funded by Government departments, Research Councils and by industry. OST is responsible for developing the LINK framework and providing support for the independent LINK Board, but does not provide funds or have any role in monitoring the research.

23 March 1999

Annex

PUBLIC CONSULTATION ON DEVELOPMENTS IN THE BIOSCIENCES: MEMBERSHIP OF INDEPENDENT ADVISORY GROUP

Beryl Allen, Womens Institute.

Phillip Campbell, Editor, Nature.

Suzanne King, Wellcome Trust.

Tom Wakeford, University of East London.

Alison Austin, Sainsbury's.

Julie Hill, Green Alliance.

Nigel Poole, Zeneca.

Monica Winstanley, BBSRC.

APPENDIX 27

Memorandum submitted by the Society, Religion and Technology Project, Church of Scotland

ABOUT THE SOCIETY, RELIGION AND TECHNOLOGY PROJECT OF THE CHURCH OF SCOTLAND

The Society, Religion and Technology Project of the Church of Scotland was set up in 1970 to raise and stimulate debate and evaluation of ethical and social issues arising out of current and future technology, employing a full time technologist. The SRT Project has been a pioneer in addressing many such issues before there was a wider recognition, and over the years it has built up a considerable reputation for the depth and insight of its expert working group studies and reports.

I have been the SRT Project Director since 1992, having previously worked in chemistry research in the nuclear energy industry at Sellafield and Harwell, in safety and risk assessment as a member of HM Nuclear Installations Inspector in the Health and Safety Executive, and in energy policy for the Chief Scientist's Group of the then Department of Energy. I am a member of the Minister for Science's group which is involved in exploring better ways of public consultation in the biosciences, to which I have made separate recommendations. I represent the UK on the Bioethics Committee of the Conference of European Churches. In this capacity I was a delegate at the recent Summit Meeting of National Bioethics Committees at the World Congress on Bioethics, in Tokyo in November 1998, and was an invited observer to the December UNESCO International Bioethics Committee.

In 1993 I set up and chaired a multi-disciplinary expert working group to examine the ethical and social issues in the genetic engineering (and in due course also cloning, since Ian Wilmut was a member of our group) of non-human life forms—animals, plants and micro-organisms. The 10 members comprised leading figures in Scotland in genetic research, agriculture, animal welfare, risk, public perception, ethics and sociology. We met and discussed regularly over five years. The work was completed in November 1998 with the publication of the book, "Engineering Genesis" by Earthscan Publications. It is possibly the most thorough study to be done so far in the UK on the ethics of non-human genetic engineering, and is unique in the lively and informed dialogue amongst scientific, ethical and social perspectives which it stimulated. This submission draws heavily on the insights of this group and of the book, but should not necessarily be taken as endorsed in every detail by all the individual members.

We also include for your information a parallel submission made earlier to the Office of Science and Technology "Review of the Framework for Overseeing Developments in Biotechnology" (listing the members of our working group)[25], and our report on genetically modified food to the Church of Scotland General Assembly, to be debated in May 1999[25].

[25] Not printed.

Our Main Submission

1. *The adequacy and quality of scientific advice*

An impressive range of benefits are claimed by scientists and other proponents for genetically modified food. We have serious doubts over how critically these have been reviewed by the Government. The initial developments coming to market concentrate not on tangible human benefits, but primarily on production characteristics or more cosmetic aspects of food. Although the initial evidence is pointing to environmental advantages in that less chemicals may be used on the land, there are also a number of serious questions about the environmental disbenefits. Public opinion thus sees little value in modified foods. The Government needs therefore to look more closely and critically at what is being offered by scientists, and why, and to do so in a much wider context than the traditional criteria of efficacy, quality and safety.

In the ethical sphere the Government has at times been naive in the way it has voiced support for some of these claims for genetically modified food, notably the claim to "feed the world". Such claims are simply not borne out by the reality of the emphasis in both research and the products coming to market. Our working group study searched at length for examples of genetic engineering research for increased tolerance to drought, acid, saline or other environmental stress which were directed towards conditions prevailing in developing countries, and found only one. Although the useful and informative reports of the International Service for Acquisition of Agri-biotech Applications[26] show some activities in developing countries, on balance the overall picture they reveal is how very far the developments in field trials are dominated by products intended for industrialised nations. It may justly be asked how far in practice genetically modified food is becoming mainly an indulgence for the rich, in the way it is currently being developed. Even if genetic modification were able to increase in food supplied per acre in the major producing regions, this provides no answer to world hunger if, as is widely accepted, one of its fundamental causes is inequitable global distribution in favour of the rich. It seems plainly illogical to assert that this problem can be overcome by a technology whose present development is clearly exhibiting a similarly inequitable orientation.

As a matter of honesty and credibility, the UK Government and other agencies either need to stop using this claim to feed the world through genetic engineering, or, better, to show very substantially greater investment in the less profitable business of feeding the truly hungry. We do not underestimate the difficulties involved, and acknowledge the validity of the argument that high tech methods are not necessarily the best solution in an indigenous context. There would, however, appear to be some potential for the hungry if Governments were prepared to "put their money where their mouth is" in this area. A major shift in research emphasis is needed if the claim to feed the world is not to be discredited as mere empty rhetoric, just like "electricity too cheap to meter" in regard to another once promising technology.

2. *The Role and Framework of Advisory Committees*

A second and equally important question of justice concerns the extent to which the applications now being implemented have the support of the society concerned, and whether adequate means exist to determine and express public viewpoints.

i. The Present Context—Posing the Problem

The cases of Monsanto's transgenic soya bean and Novartis' maize reveal deeply disturbing trends about both of these questions. Despite widespread expressions of concern, these have been allowed into the EU without either being labelled or segregated from normal, unmodified soya. Studies of the responses in different EU member states are increasingly indicative that the present deep public anxiety towards genetically modified food across Europe was sparked off primarily by allowing in these two products.

It has been suggested that considerable pressure was brought to bear by the commercial organisations concerned and by the US Government, to which the EU gave way, fearful of a trade war. There were company protestations that it was impracticable to segregate, or to label a product that would go almost everywhere through the food chain. Given that something as basic as food and as contentious as genetic engineering is at issue, the amount of influence which private commercial concerns and international trade pressure can bring on public issues seems to be out of proportion. The fact that foreign companies refused to offer segregated supplies of modified and unmodified foodstuffs seems an example of aggressive attitude towards the public of another nation. It is a case where the logic and priorities of the commercial sector appear simply to have overridden deep societal concerns. It must be asked why the situation arose in the first place, and what went wrong with the advisory systems.

One aspect is that the driving forces behind the research into transgenic food and food production in general are far too remote from public involvement and democratic accountability. Since the end of the Second World War there has been a general trend away from public involvement with food production, with the result that few work in its production or have any say about what is offered. For most people in the UK, food is what is found on supermarket shelves, with little sense of connection with what it is or where it came

[26] For example, James, C (1997), *Global Status of Transgenic Crops in 1997*, ISAAA Briefs, no 5, International Service for the Acquisition of Agri-biotech Applications.

from. Thus when any major change like genetic engineering is in prospect, it comes as an external factor to be explained to the public. The public do not have a natural point of input except at the very last stage, namely the act of accepting or rejecting the packet on the shelf. We would not agree with those who assert that is the only ethical choice that counts. It is an unnecessarily crude way for a society to make moral decisions and also a very careless way of using its resources, if the public turn out not to want the product. Where genetically modified commodities such as soya bean and maize are used in such a huge range of different foodstuffs, however, it becomes very difficult, if not impossible, for the market to act as an ethical judge about the acceptability of these products, even when labelling regimes are operated. In fact, as will be discussed below, the inadequacies of the present regulations for labelling mean that large numbers of concerned people do not have a true choice in this matter.

Moreover, the basic rationale for the genetic modifications so far on the market, or likely to come to market for the foreseeable future, is related to improved production features rather than to features of unique value to consumers. That there may or may not be net environmental benefits remains, at this point, unproven. The balance of benefit from the modification is not spread evenly over the whole population, but lies predominantly with large producers, and the costs lie with those who now cannot avoid eating these foods. To have produced such a situation is a most serious failure of the advisory system.

At a point when the public is uncertain over whether it wants this new technology or not, it seems remarkably foolish for the Government and the EU to allow onto the market genetically modified versions of the very types of foodstuffs which are so widely used in food processing that almost any food will contain them. The risk is that as with irradiated food, the public will vote with its feet about genetically modified food, and any benefits will be lost to everyone.

ii. Analysing the Inadequacies in the Present System

In our working group study, we examined what specific problems this reveals about the regulatory and advisory system. One root of the problem seems to go back to decisions made in 1992, when MAFF set up the Committee on the Ethics of Genetic Modification and Food Use, the Polkinghorne Committee[27]. Despite the profound ethical issues involved the remit of the Committee was merely to look at certain aspects, namely the eithical implications of:

- transfer of human genes to food animals;
- transfer of genes from animal species which would be unacceptable as food for some religious groups, to "acceptable" species;
- transfer of animal genes to food crops;
- use of organisms containing human genes as animal feeds.

It was only to consider food involving copy genes of human or animal origin. It was not called on to consider the ethics of plant or microbial genetic modification. Presumably this was because it was assumed that sensitivities would be less acute than those relating to animals. This indicates a prior and untested assumption by MAFF that inherent objections should be addressed only if they were based upon certain criteria—the movement of human genes to other species, or animal genes to plants—but not if they involved other modifications such as the transfer of bacterial genes into plants. Given that the vast majority of modified food applications likely to come to market were not those involving either human or animal genes, this seems an extraordinary oversight, and must be seen as a most serious mistake.

The Polkinghorne Committee did indeed recognise that other ethical issues were raised by the nature of the technology, its consequences for the environment, and issues related to the ownership or patenting of life forms, but it was not asked to explore them. The main conclusions of the committee were that there was no overriding ethical objection to the use of organisms containing copy genes of human origin as food. They suggested that the use for food production of human genes or those involving ritually unclean animals should be discouraged where alternatives were available. Labelling was recommended for food products containing copy genes of human origin, from animals which are the subject of religious dietary restrictions, and for plant products containing copy genes of animal origin which vegetarians might find unacceptable. Significantly, these labelling recommendations did not extend to food involving any other transgene, nor to a general requirement to label all genetically engineered foods. The remit given to the Polkinghorne Committee had excluded examining this most fundamental issue at this crucial stage.

iii. A Misappliance of the Advisory Committee System

The manner in which the Polkinghorne recommendations became interpreted in subsequent official and industry documents is a cause of concern. Firstly, the Government did not look at the wider implications which the Committee had hinted at. It simply followed the narrow recommendations and did not demand the labelling of all transgenic foodstuffs. More disturbingly, in 1995, MAFF issued guidelines for the public

[27] Ministry of Agriculture, Fisheries and Food (1993), *Report of the Committee on the Ethics of Genetic Modification and Food Use, (Polkinghorne Committee report)*, HMSO: London.

"Genetic Modification of Food"[28] which seemingly used the Polkinghorne Committee as the answer to all ethical questions, regardless of the above-mentioned restricted remit of the committee. The committee was cited by MAFF to justify the basic acceptability of moving genes between plants and animals which we do not normally inter-breed, despite the committee's explicit statement ". . . neither were we asked to consider the wider question of the ethics of genetic modification itself".

This was misinformation. It was further propounded in the food industry document "Food for our Future" and in information released from supermarket chains.[29] "Food for our Future" asked the question "Is it ethical?" and stated, "The UK Government set up a Committee to consider these points, chaired by Professor Polkinghorne." It goes on to summarise the conclusions, such as "Most Christian and Jewish groups in general find genetic modification acceptable". This is stated despite the fact that the Committee did not in fact draw this particular conclusion, but had indicated that significant reservations were expressed over some kinds of modification.

The narrow belief that the only ethical sensitivities were minority and religious concerns about specific types of genes then formed the framework within which the ACNFP agreed that three processed foods derived from genetically modified plants could be cleared for sale in Britain. the ACNFP argued that because the new products were almost identical to existing products, save for the specific agreed modifications, the foods required no specific labelling. It did, however, encourage firms to develop "informative labelling on a voluntary basis".

iv. Wrong Advice on Labelling—Failure to Meet the Need of Those with Inherent and Environmental Objections

Although our Church of Scotland study[30] does not conclude that genetically modified food is inherently unethical, it is very clear to us that within our society there are many individuals and groups who do object inherently to any genetic modification involving food, as well as those for whom it represents an unacceptable change in the environment. This includes many individual church members of our own and most other denominations, and many outwith the churches. It is therefore a basic question of moral justice that society has an imperative to protect those who do object by requiring compulsory labelling, and also to see they are not disadvantaged financially by having to go to specialist food shops to eat what has been until very recently "normal" food. Without a mandatory labelling system, those who object and any consumers not convinced of the arguments about environment or safety now stand to become losers. This is not merely a matter of "not being educated" but an expression of deeper values.

Given that food is essential to us all, genetically modified food presents an ethical problem of how a democratic society should decide what is acceptable food for its citizens. With the introduction of soya and maize unsegregated and unlabelled into the UK, the advisory and regulatory system failed in a most serious and disturbing fashion. It is of the utmost importance that it is changed to prevent any similar occurrence in future.

The changes that have so far been made do not, however, meet this basic requirement. The EU's subsequent regulation that genetically modified food should be labelled if scientific tests could detect the presence of the new genes or protein derived from them has frankly missed the point at issue for a large number of UK citizens. The mandatory labelling is relevant only to those who have a safety concern over whether they are literally eating strange genes. For all those who for the reasons stated above object to the very process of genetic modification of food, regardless of whether the products remain detectable in a particular foodstuff, the labelling system does not address their concerns. They have no system for informing them whether they are eating food which is for them fundamentally unacceptable. We do not have statistical data to estimate how many people fall into this category, but on the basis of opinions expressed to us among church members, we suspect it could be a very large number indeed.

This represents a continuing failure in the advisory and regulatory system to meet the needs of numerous citizens. Its roots lay in the mandate given to the Polkinghorne Committee and the conclusions which MAFF drew from it—that the ethical concerns of genetic modification in food were not about general objections, but were primarly to do with certain genes regarded as significant by specialist groups, which could be met by scientifically demonstrating their absence. This is a gravely mistaken approach. One cannot reduce a general ethical or environmental objection of this nature to a scientific test of composition.

However inconvenient it may be, the only way to redress this situation would be to require the mandatory labelling of all foods where the process of genetic modification has been used, regardless of whether they are "functionally equivalent" from the point of view of the limits of detection of a scientific test. In December 1998, the House of Lords Select Committee baldly declared this impracticable,[31] but it gave no substantial

[28] Ministry of Agriculture, Fisheries and Food (1995), *Genetic Modification and Food—A Guide from the Food and Safety Directorate,* HMSO: London.

[29] Food and Drink Federation (1995), *Food for our Future,* Food and Drink Federation: London.

[30] Church of Scotland (1999), *Genetically Modified Food,* Report to the 1999 Church of Scotland General Assembly, Society, Religion and Technology Project, Board of National Mission, Edinburgh.

[31] House of Lords Select Committee on the European Communities (1998), *Second report: EC Regulation of Genetic Modification in Agriculture,* 15 December 1998, HMSO, London.

reason why. It appeared not to have given this point the serious consideration it deserves. If the committee is correct, we would require to see substantive evidence to back up its assertion.

On the contrary it would seem that the Lords' opinion can be challenged by comparing with other industries where the ability to trace the origins of materials is seen as important. As a former research worker in the nuclear industry, I had, in law, to be able to account for the origins, present whereabouts and fate of every last fraction of a gram of plutonium which I handled. If an administrative system can be set up to trace the detailed provenance of such materials as plutonium, it seems entirely reasonable, therefore, that a system of tracing for genetically modified food could be instituted. Rigorous traceability will also be required for cattle exports in the wake of the BSE crisis. It is not so much detectability but having an appropriate administrative system, and not so much feasibility as the lack of a will to do it. It is significant that some supermarket chains have been able to locate non-genetically modified soya and maize and to do so apparently without significant cost. Cost should not therefore be assumed automatically to be a barrier. Indeed, from a market economic point of view this would be an element of the true cost of genetic modification, to be borne by the relevant foods.

There is a clear moral obligation for society to provide the means of exercising real choice in this matter. The present system is not offering that choice.

v. The European and International Dimension of the Advisory Process

The approval of genetically modified maize by the European Commission in December 1996 without publishing its justification has led to much criticism and a refusal by some EU member states to comply, and a censure vote by the European Parliament. The EC has since put pressure on Austria that its opposition was contrary to trade agreements. These matters raise some disturbing questions about the European regulatory system.

The European Commission maintains that, in line with its various treaties, it has not legislative competence to decide for member states on ethical matters on biotechnology. This was the response we received from the Commission when we raised the question of ethical committees and the EU Biotechnology Patenting Directive. In the case of Austria, however, the EC is in effect seeking to override the ethical stance of one of its member states. *De facto* the EC is making an ethical judgement that the economic criteria expressed in the treaties concerning the internal market have overriding importance over any ethical objections of member states. Yet, by the terms of its own treaties, the EC is not competent to make such an ethical judgement binding on a member state.

There are wider international concerns of a similar nature. It has been pointed out that once the US Government authorised modified soya and maize and the producers decided not to segregate, the only way for Europe to have kept them out would have been to ban all US soya and maize imports and thereby risk a major trade war. In the face of such pressures, the opinion and values of the people of Europe seem to have been of only marginal importance. Monsanto has belatedly admitted that it did not appreciate how different attitudes to biotechnology are between the Europe and the US. All this raises very serious questions of how far the present systems enable the UK Government to take responsibility to ensure that the values of its own citizens are not at the mercy of the whims, private motives or ignorance of foreign companies.

In the present system of regulation in place in the UK, ethics seem inevitably to be overridden by the terms of trade. Citizens' just rights are made secondary to international legilsation. The power of the WTO is of particular concern, in that an apparently unaccountable panel of experts seems to be able to adjudicate over which ethical values of a sovereign state and its citizens can be allowed to interfere with "free trade". Steps must be taken by HM Government in the renegotiation of the WTO treaties that no such external treaty should have the power to impose values at odds with the majority of the UK people. Here surely is a test case to see if parliamentary democracy has any meaning when it really matters.

vi. Conclusion about the Advisory Process

The UK advisory system regarding genetically modified food reveals a number of very disturbing features. Firstly a range of inherent and other wider objections to genetic modifications appear not to have been considered in the original advisory process, and thus became largely marginalised. In retrospect, this was a serious misjudgement.

Secondly, since the criterion for labelling was only very narrowly based, those with inherent or environmental objections are unable to avoid the products to which they object. Despite the various changes in labelling regulations, this unacceptable situation remains unchanged. It is not sufficient that labelling is required only where the relevant DNA or proteins can be detected in a scientific test. It must be extended to where genetic modification has been used as part of the process. Claims that this is impracticable are challenged by reference to the traceability required with regard to sensitive materials in other industries. The true criterion is whether it matters enough.

The circumstances surrounding the importation of unsegregated and unlabelled soya and maize into the UK and Europe reveal a serious failure of democratic accountability to the public at national and European

level, on something as basic and important to us all as food. This leads us to consider what changes are necessary in the advisory system and also in regard to what is permissible for a member state to object to under both EC and WTO treaties.

3. *Needing Overall Committee on the Ethics of Non-human Biotechnology*

Decisions over ethically sensitive questions such as genetically modified food and other products need to be made on behalf of society in full appreciation of the variety of social attitudes, values and preferences. From the foregoing critique it is clear that no commitee is currently fulfilling this function to any real effect. One way to achieve this would be to set up an ethical commission for non-human biotechnology, which operated with full public disclosure of its evidence and its deliberations. This might help to defuse at least some of the more contentious issues surrounding the release of GMOs. In the Parliamentary discussion on the Environmental Protection Act (EPA) 1990, there were demands for the setting up of such an ethical commission. Proposals for the remit of this commission ranged from purely ethical concerns to the assessment of products in terms of their environmental benefit and/or socio-economic need. For example Brian Gould MP argued:

> "We can easily imagine the impact that GMOs might have in the hands of self-centred, multinational companies with laser beam objectives . . . It calls into play the increasingly familiar worries about the moral propriety of mankind playing God . . . some people will be able to manipulate life for their own specific purposes." (Hansard, 6 March 1990, pp 952-3).

The Government of the day rejected the idea of an ethical commission partly because the idea of social progress was equated in their minds with technological advance, which they felt would be obstructed by such a commission. The short-sightedness of this view is one of the primary conclusions of our SRT working group study.

The arguments for such a committee are made far more fully in our enclosed submission to the Office of Science and Technology regarding the regulatory system[32]. In particular we would stress that it would only be effective in addressing the serious failures outlined earlier in our submission if it also incorporated a much greater degree of public involvement within the committee, in its public consultation procedures and in what it is seen to have done with the evidence it receives in those consultations. The present systems affecting non-human genetic engineering are to greater or lesser degrees inadequate. A significant revolution is needed if the existing problems are not merely to be perpetuated.

4. *Representation on such a Committee*

The current policy of including public interest representatives in ethical decision making bodies is based on the notion that decisions of the committee should reflect a range of values as well as technical knowledge. It has been found in the past, however, that members who lack scientific expertise have exerted very little influence on committee decisions. As a result, a semblance of consultation has been conveyed, but without having any real substance.[33] For instance, most risk regulators have been educated in the scientific-rationalist tradition and see no place for personal values in decision making on risk, while being unaware of the personal values they themselves bring. When regulators are asked questions about value judgements, the answer generally comes back in a form which has interpreted the words "value judgement" to mean scientific uncertainty, rather than associating it with any system of human values. The intended legitimation of the GMO thus runs the risk of being at best rather hollow, and at worst portrayed as a sleight of hand.

Much also depends on the extent to which the body is seen to be saying "no". If its narrow membership inclines it never or seldom to do so in an area which the public perceives to be sensitive like genetically modified organisms, people will tend not to believe that its members are exercising their critical faculties or else see it as a "closed shop", because they see no tangible evidence to the contrary.

The balance of membership of various official regulatory, safety, advisory and ethical committees needs to be widened considerably, to reflect a greater diversity of view than has hitherto been the case. It is not sufficient to have the token "green" or "consumer" person if the bulk of a committee is dominated by industry representatives. This may satisfy the letter of the law, for the purposes of answering a parliamentary question, but it misses the spirit of it.

Committees also tend to hear public evidence and then do everything else in private, without any further intermediate discussion with the public. This is not real dialogue. The model for such assessment needs revising. More satisfactory approaches appear to exist in, for example, the Netherlands national committee for transgenic animals. Here the provisional findings of the committee are opened to a period of public comment, and the report is revised in the light of what comments were received. Its final recommendation to the Government Minister, must be made public and must show clearly what its response has been to the comments received, and, if it has disagreed, on what basis it has done so.

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[32] Not printed.

[33] Jasanoff, S (1986), *Risk Management and Political Culture*, pp 59–59, Russell Sage Foundation, New York.

At the local level too, procedures need to be established whereby committees adjacent to both experimental and production sites are kept informed and consulted. It is of much concern that in the extension of the requirements under the Animals (Scientific Procedures) Act to include ethical aspects and lay membership on the relevant local committees, neither lay members nor face to face dialogue were considered to be mandatory. In the Society, Religion and Technology Project study one of the most important outcomes of our work was the importance that the scientists had regular face to face dialogue with lay people who were expert in other disciplines. Having to defend their viewpoints outside the scientific research and policy peer groups was not only immensely stimulating for all concerned, but it revealed the importance of a much wider set of social and value questions than the scientists themselves had realised, and which they would have previously been apt to dismiss out of hand. We would greatly recommend this approach of regular and continuing inter-disciplinary discussion for researchers and policy makers engaged with the area of genetic modification.

In our evidence to the OST, we say that there is no one way that public participation can be achieved. The public consensus conference and citizens' panels are valid under some circumstances. Working groups like our own could be an important way of getting scientists engaged and aware of public and ethical concerns. In Scotland, public surveys are indicating an overwhelming majority of Scots desire a very much greater degree of public participation in the political process than is currently the case. Reflecting this, the Consultative Steering Group for the Holyrood Parliament have now laid down that the committee and pre-legislative consultation arrangements will be very much more open than those in the Westminster Parliament. The working practices which will be developed might well be of much value for guiding comparable changes that seems so clearly needed south of the Border.

5. *Place of Intrinsic Concerns in Ethical Advisory Committees*

For many years there has been a tradition among many scientists and people of a rationalist frame of mind to dismiss intrinsic ethical arguments as non-rational and emotive. They are seen as of no value or significance in modern societies where rational debate and empirical evidence are the principal canons of authenticity and truth. Intrinsic arguments imply moral absolutes, which are associated either with God or with outmoded philosophical systems, and therefore not to be entertained. Alternatively, they are associated with certain structures in society—groups who have a particular agenda, like the environmental lobby or a social elite. At best, intrinsic arguments are merely one's private view, which cannot be accorded any privileged status, and must be put to one side in debates in a plural society.

Since such beliefs are moreover perceived to be unresolvable by rational argument, they ought therefore to be excluded from discussion. If one does not happen to agree with the position put forward, this can lead to problems in finding common ground on which to debate an issue, and especially if there are two opposing principles involved. Some perceive it to be more difficult to engage in meaningful debate with someone who says, for example that to genetically engineer a mouse to be hairless is wrong in principle, than someone who maintains that it is wrong to do so to find a cure for human baldness, because the reason is trivial compared with the suffering to the animal.

For these various reasons, it has long been close to orthodoxy in many influential spheres of government, academia, industry and commerce to dismiss intrinsic views almost entirely from consideration. The explicit inclusion of intrinsic questions in the Banner Report on emerging animal breeding technologies was a welcome and notable exception to the trend[34].

Yet this apparent expression of liberal tolerance hides the reality of the deep-seated values and belief systems which underlie all our lives, whether consciously or not. Intrinsic ethical arguments are by no means limited to religious believers, or to environmental groups. Indeed, most people hold them in some form. Whether as scientists, journalists, civil servants, company directors, or simply as voters and consumers, most of us hold certain fundamental and often unverifiable beliefs about the cosmos and human life. The advocates of genetic engineering are likely to be just as much influenced by their own intrinsic beliefs and prior value commitments about the nature of life, humanity and the environment as are its opponents.

For example strongly held beliefs about science fall into the category of intrinsic belief. It is maintained surprisingly often that scientists are claimed to be engaged in a technical procedure which is ethically neutral, and value considerations arise only in judging its applications. This is, however, a serious and short-sighted fallacy. The science of genetic engineering, the interpretation of its scientific data, and the evaluation of its risks and benefits are all laden with the values which are written into the enterprise. For example, the basic assumption that it is appropriate to reduce the physical environment to isolatable genetic, organic and chemical processes, which can be manipulated by the scientist, is a value judgement about the nature of reality and human action within the natural world. Such assumptions as this are so familiar that they are apt to be taken for granted, without recognising that they involve intrinsic ethical judgements. The scientific and technological perspective is as value laden as any other.

[34] Ministry of Agriculture, Fisheries and Food (1995), *Report of the Committee to consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals*, (Banner Committee report), HMSO: London.

Earlier this century, Max Weber drew an important distinction between what he called value rationality and instrumental rationality.[35] Value rationality refers to behaviour that is logically consistent with a particular value position which a person holds. Like inherent principles in ethics, in its purest form value rationality would not take consequences into account, as in the standpoint that rejects genetic engineering as intrinsically unacceptable. In contrast, instrumental rationality takes account of the consequences of actions, as in utilitarian philosophy and various forms of cost-benefit analysis. It is a calculative approach which judges the appropriateness of means to reach given ends only in so far as these can be identified and quantified. Ethical endorsement of particular actions or policies enters in our judgement on the desirability of the consequences, not the means used. The key point is both of these are forms of rationality, but each uses reason on a different basis. It is not the case that by definition the instrumental approach is rational and therefore valid, and that the value approach is irrational. A technology like genetic engineering has not appeared out of a vacuum, but has various stakeholders who each have implicit values in the ends that they seek. Moreover, for all its cognitive power, the role of scientific knowledge is not straightforward. Scientific rationality will not tell you what to do with its knowledge. Different areas of science, like ecology and molecular genetics, may differ over the evaluation of particular risks. Scientific rationality has to be interpreted and evaluated within extra-scientific frameworks with various ethical, political and economic dimensions.

At an institutional level, therefore, a denial of the validity of intrinsic arguments and value rationality in ethical debate can present real problems to the democratic process. Because reason has such powerful positive connotations the accusation of irrationality by scientists or others against an opposing standpoint has often become a tool of power in committee discussions or public debate. One group dismisses opposing views as irrational (usually referring to value rationality) in order to marginalise the position of others. This is especially of concern over the "token consumer" on advisory committees, who can easily be marginalised not only numerically but in the very mode of rationality. If committees are primarily composed of people from a scientific approach to rationality, this pre-ordains certain relationships of power and influence—as insiders or outsiders—in a way which undermines any real public engagement. The danger for those who are in positions of power is to assume that intrinsic beliefs are things which only the opponents of the technology have, and to be unaware of their own, and of the considerable influence that these may already be having. As level a playing field as possible is therefore needed about basic assumptions, in order to avoid the abuse of power. Our book *"Engineering Genesis"*, and the working group which has produced it, attempts to redress the balance.

Finally, it is important to develop a political culture in which politicians are educated to appreciate the scientific and ethical issues as well as the political and commercial aspects. Parliamentary select committees, such as that on science and technology, can be quite effective in obtaining scientific data, but may not be geared to a comparable level of ethical assessment, nor to a critical examination of the social context in which the questions are framed. Who will "guard the guardians" is a continuous educational task, a prerequisite for informed judgements. Those who have responsibility for making such decisions should know the range of alternatives and why they have made their judgements in the way they have. This can never be done infallibly, but it is the grounds on which representative and responsible political action can be taken.

It is not adequate to produce a culture either in which experts are treated as god-like, or one in which they are totally dismissed because they disagree with each other. We need to develop better ways in which citizens can develop the faculty of questioning and evaluating what it is they are being told. There is no substitute for an educated public. It is out of such a climate that politicians and experts need to come in the first place.

23 March 1999

APPENDIX 28

Memorandum submitted by Dr Katherine M Venables, Senior Lecturer in Epidemiology, Imperial College School of Medicine

Introduction

I am a Senior Lecturer in Epidemiology at Imperial College School of Medicine. I am a member of the Advisory Committee on Releases to the Environment (ACRE) and for a brief period was a member of the Advisory Committee on Novel Foods and Processes (ACNFP).

Memorandum

Thank you for asking me to provide information on this matter. I have already written to Dr Linda Smith of the Department of the Environment Biotechnology Group. I would suggest two changes in the current system:

1. I think the Government needs advice from a wide range of sources at a very early stage in the genetic modification process and long before there is great pressure on government and on commercial organisations

[35] Weber, M (1978), *Economy and Society*, University of California Press: Berkeley (an English translation of a very much older original).

to market a GM product. This advice should include not only wide ranging scientific and public health advice, but also advice from ethical and consumer affairs perspectives.

2. In my opinion, it would also be helpful for government to have a much wider range of medical advice than it has at present. This should include toxicologists and also public health specialists, particularly from a perspective of food safety.

APPENDIX 29

Supplementary memorandum submitted by Dr Arpad Janos Pusztai

Concerning the allegations made by Professor James as to my part in the controversy and the respective responsibilities of the Rowett Research Institute and myself.

Sequence of events

The general complaint of Professor James is that I had released information into the public arena, which had not been previously published. The precise nature of the information I am alleged to have published, how and when this took place remains obscure. What is apparent from the following, however, is that Professor James' version contains a number of inconsistencies and indeed, contradictions. It should also be noted that I participated in the "World in Action" programme with his full support, he knowing that I had little experience of such an event. Professor James had ensured that Hilary Robertson, the Rowett's in-house public relations expert, was present during the filming, but evidently no thought was given to the manner in which Granada would advertise the programme or the content of any Press Release relating to it. Now that I see how these things work, I would have expected Hilary Robertson to have had a significant input in this, or, at the very least, be alerted to how Granada would be presenting the programme to the public.

As it was, in the absence of any preparation or forward thinking by the Rowett, I was left to deal entirely on my own with the press interest that emerged on the evening of Sunday, 9 March (before the transmission of the programme), as well as dealing initially with further press and other enquiries on the morning of the 10th.

The Press Release that Professor James issued later on the morning of the 10th was without any reference to me and the additional Release sent out by Mr James Provan on behalf of Rowett (also without reference to me) only made matters worse. It is totally untrue, as alleged by Professor James, that I had been consulted regarding the content of the Releases or that I had proposed changes. They were put together and sent out without any reference whatsoever to me. In so doing, the Rowett itself actually made public data that hitherto had not been published. The relevant portion reads as follows:

> "The preliminary information suggests that the potent insecticidal lectin concanavalin A obtained from the South American Jack Bean if inserted into potatoes will have no immediate effects on rats fed a diet containing these GM potatoes. No obvious intestinal damage occurred but the rats had slightly stunted growth when tested after 110 days' feeding and the response of their lymphocytes to mitogenic stimuli was about half that of controls".

It should be noted that in this Press Release the Rowett claimed that the work was done with GM-Con A-potatoes whereas in the Programme I never mentioned which gene we had used. Although all GM-potato work was done with GNA-GM-potatoes, there was no mention of this in the Press Release. It is inconceivable that, had I seen this, I would not have insisted on drawing attention to our work with GNA. Also the Release refers to "intestinal damage", that is clearly an experimental detail. I never mentioned anything about intestinal damage in the three press interviews I gave on 9 August or in the TV broadcast on 10 August (not even later as this was Dr Ewen's work which he completed in November and in any case it was with GNA-GM-potatoes!). In fact, no gut histology had been done with Con A, not even with the Con A-spiked parent potato fed rats—I am at a total loss to understand where Professor James obtained this incorrect information from. Again, had he shown the Press Release to me I would have corrected this. Finally, in the last sentence Professor James gives an undertaking that these preliminary studies will be extended and published as soon as possible. It is quite significant that "further information" to be had was "from Professor James" and not from me.

As from the morning of 11 August I was told not to speak further to the press, with which arrangement I was entirely happy. It was not, however, until the morning of 12 August that Professor James told me I was suspended. Even then it was not clear how long my suspension would last nor why. However, I was told on 12 August, when I was suspended, that my contract expiring at the end of the year would not be renewed. This notwithstanding that the experimental programme was set up to run through to mid 2000 and up to which time it had always been understood that I would remain with the Rowett.

Dealing with the various stages of this matter:—

1. Precisely what I am alleged to have said in the programme that Professor James considered a transgression of Rowett policy or a publication of unpublished information has still not been specified.

2. If it is the content of Granada's own Press Release of 9 August with which Professor James is in conflict that cannot be placed at my door since the release did not reflect my contribution to the programme.

3. The allegation, that I had claimed to have carried out experiments involving GM-Con A, which promoted Professor James' Press Release of 10 August, is totally wrong. No such claim had been made by me, since no such experiments had ever been conducted by me.

4. The Rowett as part of its "damage limitation" endeavours issued the two Press Releases on the morning of 10 August, neither of which I saw prior to their release. Both releases were issued before the screening of the programme and without any consultation with me. They created the wholly inaccurate suggestion that I had referred to experiments involving Con A (which I never did) and that any publication relating to those alleged experiments (which never took place) would be in breach of my obligations.

5. Professor James explains that it was not until 11 August that he "discovered" that the GM-Con A experiments, which he had rushed into print about, and which he appears to have convinced himself that I had claimed to have conducted, did not exist. Upon that "discovery", he blamed me for the fact that he had issued the flawed Press Release the previous day. As a further innovation, was his complaint that had I made reference to such an experiment, that amounted to release of unpublished material. I find the sequence of this thinking and the consequences that flowed, quite extraordinary.

6. Again, notwithstanding these confusions, Professor James still wanted me to explain the background to my research to MAFF hence the letter I drafted to Mr Wotherspoon. I prepared that on the morning of 10 August, making the point that we had never conducted any GM-Con A feeding experiment. Professor James read the draft around 10.30 am on that day and made the hand written amendments in which he persisted in referring to GM-Con A potato work, contradicting my own clarification on this point. From this it is apparent that he had still not understood the work on which I was engaged. I have a copy of the amended draft letter: I do not know if that letter in its original or amended form or indeed a different letter went to MAFF.

7. By the afternoon of 10 August I had ceased to have contact with journalists.

8. On the morning of 12 August I was called into Professor James' office and abruptly told by him that I was being suspended. That after 37 years of service and in which my commitment to the work of the Rowett was total. I asked why this draconian move and was told that it was "to protect" me.

9. I was immediately banned from my laboratory, which had virtually been my second home for those 37 years. I was excluded from my colleagues, my records were denied me. Beyond that, far from protecting me, my reputation was put publicly in question.

10. Before the Science and Technology Committee of the House of Commons, Professor James persisted in his allegation relating to unpublished material and my responsibility for the non-existent GM-Con A experiment. He continued to maintain that his reason for the suspension, which led to the ultimate dismissal (or non-renewal of my contract as he seemed to prefer) was to protect me and my reputation. Of course, the exact opposite was inevitable and my professional standing was seriously affected.

11. In revisiting all the events and their actual sequence, Professor James has elsewhere complained that I had given information to the media (presumably meaning the GM-Con A information) which was not only false, because it did not exist, but which, had it existed, would have been an unauthorised publication! Again I must emphasise that in the programme I made no reference whatsoever to any such experiment (for the obvious reason that none had been conducted) nor did I volunteer any such information when challenged by journalists on the Sunday evening. It was they who introduced the topic to me and I can only deduce that they had obtained these references from another source before speaking to me.

12. It reflects totally the way in which on the Sunday, in response to Granada's own Press Release issued that day, I was caught up in a situation not of my making. Beyond that there was no attempt to provide me with support from the Rowett PR and I was left very much to my own devices.

13. Out of the blue, in the course of that quiet Sunday evening at home with my wife, I was telephoned by professional journalists questioning me in terms that suggested that they had already been primed over certain work that had been said to have been conducted in our laboratory. It was Mr Nigel Hawkes of *The Times* who initiated the reference to Jack Beans. Since I had neither referred to it in the programme nor brought it into the conversation with him, that information could only have come from another source and it is not for me to speculate what that source was. My mistake (and I referred to my naivety before the Committee), was to try to explain the science to journalists who appeared to have already been given certain information from whence I cannot say, but where they still had basic misunderstandings. I have to say I did not recognise also the level of sensationalist writing that they were aiming for. The following morning, in an early TV broadcast, Mr Dam Verakis of the Monsanto Corporation himself commented on the unreliability of GM-Con A experiments. By attributing my findings to such experiments, it provided an opportunity for rubbishing my views. The reality, however, was that my conclusions had been reached through a different route, the content and value of which was in fact never challenged.

14. Later that morning I was telephoned by Mr Wotherspoon of MAFF and it was my conversation with him that Professor James heard, it was not a journalist, as he alleged before the Committee. Indeed, it was consequent to this discussion that Professor James asked me to draft the letter referred to in paragraph 6 above.

15. It was Professor James who put me in the firing line by agreeing that I should appear on the TV programme, by not anticipating the need to give prior approval to any publicity matter issued by Granada, and then leaving me to cope. He knew that I was no media person, I had no training or competence in this field. It was he who chose the PR to sit in while the interview with me was filmed. He must have realised the possible implications of stepping into the public arena—which frankly I did not. Moreover it was an important omission on the part of Rowett and the PR that they did not demand to approve the Granada Press Release for the proposed programme.

16. It is apparent that the panic that set in and produced the over hasty and the ill-considered Press Releases on the 10 August was the real cause of the crisis. The level and intensity of the reaction was, in any event, very surprising and did seem somewhat disproportionate. It was certainly right that the scientific and technical information should be corrected, but I question whether that alone should have warranted all the reactions that emerged.

17. It would certainly have been preferable to have guarded me from the media. I had not sought it, and found myself drawn into discussion and into areas where inaccurate information appeared to have been given previously to journalists. It certainly did not come from me, so that in my conversation with them I found I was starting from a different position to that which was the essentials of my contribution to the Granada programme.

23 March 1999

APPENDIX 30

Letter to the Committee from the British Medical Association

Thank you for inviting us to submit written evidence on the areas outlined in the press notice dated 11 February 1999. Our comments are as follows:

The Adequacy and Quality of Scientific Advice at Present

Scientific advice on GM food does not at present provide a consensus on a number of important issues; for example, there are no clear labelling standards for GM foods, and in particular no threshold levels have been set to determine when a food is to be considered genetically modified.

Scientific advice given to the public should be clearly stated and widely available. To receive and understand the advice offered, the public should be encouraged through the education system at all levels to develop a greater scientific literacy and understanding; this cannot be left to the food industry.

The Role and Framework of the Advisory Committees

It is questionable whether the current process for assessing GM foods adequately protects the consumer from potential adverse effects. Information on toxic or allergenic effects of GM products are included in their application to the ACNFP. However, the current system only requires identification of known or existing allergens. Long term animal feeding trials are necessary to assess cumulative allergencity and toxicity, and require much more research funding.

The new Food Standards Agency will oversee the work of ACNFP, and should take an increasingly central role in the decision making process on GMOs. We agree that the Agency should be accountable to Parliament via health ministers. It should have the remit to veto the introduction of new agricultural procedures (eg pesticides/GMOs) on safety grounds.

The Ability of the Current System to Respond to Rapid Scientific Developments

The system should be able to respond rapidly to scientific developments; however the nature of Genetically Modified Organisms makes them difficult to "recall" in the event of any new scientific knowledge indicating adverse effects. The precautionary principle should therefore be applied from the outset, and time must be allocated for long-term assessment of scientific developments before release of GMOs into the environment.

To What Extent There is Value in the Proposal for an Overarching Body to Advise on and Oversee all Genetically Modified Food Issues

At present the "case by case" approach to GMO regulation ignores the cumulative effects of GMO releases, and has been criticised by bodies such as The Royal Society and Royal Commission on Environmental Pollution. Consideration should be given to the possible interactions between different types on GMOs once they are released into the wider environment.

An overarching body, in the form of the Food Standards Agency, could advise on all issues relating to genetically modified foods, once they have been considered by the appropriate existing committees.

THE CAPACITY OF GOVERNMENT TO BE AN "INTELLIGENT CUSTOMER" FOR THE ADVICE IT RECEIVES

Government should ensure that all Members of Parliament are provided with comprehensive briefings on key issues surrounding GMOs—the provision of technical and policy information from professional bodies for direct use by MPs should continue to be encouraged. Select committees do much to assist government by presenting recommendations and valuable reports.

In being an "intelligent customer" for scientific advice government must recognise that a comprehensive review of each consultation document and preparation of a response may take up to eight weeks for large professional organisations who may require to canvass the views of numerous committees and subcommittees.

In order for Government to receive the best scientific advice, it should directly fund more scientific research and encourage a culture of greater openness and accessibility. In the case of Genetically Modified Foods, this may be achieved through funding long-term research, for example into long-term animal feeding trials, and publication of the results.

I hope these comments are of assistance.

22 March 1999

APPENDIX 31

Memorandum submitted by Compassion in World Farming

1. Compassion in World Farming (CIWF) is the leading UK organisation working to improve farm animal welfare. Although our focus is primarily on animals on farms, in transit and at slaughter, we are also concerned about the use of genetic engineering technologies on farm animals and the use of genetically engineered substances (eg BST) to increase productivity. Milk from BST-treated cows is the only animal-based genetically modified product which has so far entered the human food chain in the UK.

2. Although there are no applications for marketing meat or products from genetically modified animals in the UK at the moment, there has been an application to the Government to market meat from the "failure" animals from genetic engineering experiments.

3. CIWF's position is that we are opposed to the genetic engineering of farm animals and to unnecessary productivity enhancers such as BST. We have extensive evidence from published scientific papers which catalogue the suffering caused to farm animals in genetic engineering experiments. There is now also overriding evidence on the serious animal health and welfare problems caused to dairy cows by BST treatment.

4. CIWF's experience of lobbying the Government on the health and welfare aspects of BST has not been a particularly happy one.

5. The reason for this appears to be that the Government was taking advice on BST from the Veterinary Medicines Directorate, because BST is classified as a veterinary drug. It is therefore measured against the traditional criteria of quality, safety and efficacy. There is no independent assessment of the impact of this product on animal welfare.

6. Yet this is not a therapeutic drug, but is intended to be used as a productivity enhancer. The ethics of its use have also not been assessed.

7. The situation therefore is that a new drug produced by biotechnology and intended as a growth promoter and which has now been shown to have severe adverse effects on the welfare of treated cows could get the go-ahead simply because it "works".

8. Therefore there needs to be a committee of some kind which assesses the welfare implications of new biotechnology products which may be applied to animals. This role could be assigned to the Farm Animal Welfare Council.

9. There is another problem regarding the welfare of genetically engineered animals and cloned animals. Whilst in the laboratory development stage, their welfare should be covered by the Animal Procedures Committee (APC). (Although it must be added here that we are seriously concerned at the ease with which permissions for experimental work are granted, in view of the poor welfare record of genetic engineering and cloning work).

10. However the welfare of cloned and/or transgenic animals needs to be assessed for a long time into the life of the individual animal and into subsequent generations of genetically engineered animals, where problems may come to the surface. By this time the animals could be in an on-farm situation. It is urgent that before such "releases" occur, a system is in place for monitoring their welfare and the welfare of future generations.

11. Apparently ACRE again has no"animal welfare brief". It is vital therefore that an ethical assessment is made of any such "releases" from the laboratory to the farm.

12. Again it is possible that the ethical decision-making could be included within the brief of the Farm Animal Welfare Council. Ongoing monitoring of welfare would need to be carried out by veterinary surgeons, preferably those who had obtained the Certificate in Animal Welfare.

13. CIWF does not feel that it is our brief to comment on whether there should be an overriding body to advise and oversee all genetically modified food issues. However, we do believe that there does need to be a committee which oversees all developments in which farm animals are involved, either as trangenic animals, rejects from transgenic experiments or animals to which biotechnology products are given. This body should have a strong emphasis on both ethics and practical animal welfare expertise.

14. For example, CIWF is convinced ethical questions are not addressed adequately in the current system, eg the UKXIRA appears to have an oversight brief for xenotransplanation, but no remit to rule against (or for) any xenotransplant activity on ethical grounds.

15. Perhaps an Animal Ethics Committee could oversee all novel uses of animals, new biotechnology procedures and products and assess the ethical implications of their application to farm animals. They could seek advice from the APC and the FAWC but also from interested groups such as CIWF, which have a direct interest in farm animal welfare.

16. Our experience with BST has forced us to the conclusion that the Government's policy is often based on the advice it receives from its own agencies or committees. It is essential therefore that such committees are dealing with all the issues raised by particular problems.

17. CIWF's experience leads us to conclude that farm animal welfare and the ethics of farm animal use have not been adequately addressed and that future developments in genetic engineering of animals may reveal further gaps in the advisory process.

I do hope your committee will be able to address these serious concerns.

References:

1. A report on animal welfare aspects of the use of bovine somatotropin. Animal Health and Welfare Committee of the European Commission. March 1999.

BST: A Distressing Product: An analysis of the health and welfare problems of dairy cows injected with BST. Compassion in World Farming. 1998.

26 March 1999

APPENDIX 32

Memorandum submitted by GeneWatch

GeneWatch is an independent organisation formed in January 1998, specialising in the ethics, risks, science and regulation of genetic engineering. GeneWatch is concerned with the processes which drive and sanction the introduction of genetic engineering; provides analysis of safety regulations; identifies which issues have been neglected; analyses the potential social, environmental, human health and animal welfare implications; and researches who is behind the developments. GeneWatch believes that genetic technologies may lead to medical and other advantages but society has a right to know what the moral implications are and participate in decisions about what risks we are taking.

Scientific advice has become central to decision making on genetically modified (GM) crops and foods in the UK. Therefore, GeneWatch welcomes the opportunity to give its opinion of the present system to the Science and Technology Select Committee.

(i) The Adequacy and Quality of Scientific Advice at Present

GeneWatch believes that the scientific advice given in relation to the environmental and human safety of GM foods and crops has not been of top quality, being neither scientifically robust nor imaginative. This is partly because of the narrow boundaries of the safety debate and partly because the people involved tend to have a commitment to the technology and so do not have a critical "edge". As a consequence an optimistic perspective of the risks is supplied to decision makers which is not scientifically justified.

When evaluating the environmental safety of GM crops, for example, the remit of the advisory committee (until October 1998 when the Environment Minister expanded the areas to be addressed) had been restricted to the possible impacts of the GM crop itself and not their knock-on effects on agriculture and biodiversity. Because biodiversity was not a recognised dimension of past assessments, scientific data has not been collected and no evaluations made. The pressure for a broadening of the base of the environmental assessment did not come from the Government's scientific advisors (either in Whitehall or on the statutory advisory committees) but from outside groups who were asking difficult scientific questions. Because the scientific

advice has been so unquestioning on issues such as this, it has left the Government exposed to criticism over the justification for its decisions.

Scientific advice about the potential for health impacts of GM foods has been similarly uninspiring. This can be seen most clearly in the uncritical acceptance of the principle of substantial equivalence among those advising on GM food safety. According to substantial equivalence, if a GM food is deemed chemically the same in all important respects to the non-GM version, it is considered safe. Of course, what is an important difference is the difficult scientific question. In the UK, scientific advisors have been content to take as sufficient evidence of substantial equivalence, gross chemical comparisons and measurements of products which are already known to have the potential to be toxic (erucic acid in oilseed rape, for example). There has been no attempt to examine foods for unexpected changes or search for methods to do this. Whilst difficult, there are other approaches which may help identify any effects of the genetic modification (due to disruption of other gene sequences, for example) which could be explored.

In contrast to the UK, the Netherlands' Government has recognised the limitations of substantial equivalence, has commissioned research and is proposing additional analytical methods and approaches. These include mRNA and chemical fingerprinting of GM foods and intestinal tract modelling[36]. This innovative thinking has been sadly lacking in the UK. Again politicians relying on scientific advisors are left exposed and subject to criticism when the fundamental assumptions upon which safety assessments are based are not being questioned and tested by their advisors.

(ii) The Role and Framework of Advisory Committees

There is a danger that scientific advisory committees such as ACRE and ACNFP are substituting for proper political decision making and accountability. There is a tendency in British politics and among scientific advisors to build the fiction that a final pronouncement can be made saying a GM crop or food is safe or not. For example, in a recent written parliamentary answer, the Food Safety Minister, Jeff Rooker said:

> "*All genetically modified crops which are permitted to be imported into the UK have been approved following a rigorous assessment of their safety. It is therefore not possible to require segregation under the WTO*".

In this way decision making is deferred to scientists who are supposed to be able to make unequivocal decisions upon safety which politicians can then use as a justification for their position on a subject.

Of course, the risks associated with GM crops and foods are complex and broad in scope, the science is new and uncertain and the risks not simply physical in nature. The risks include: genetic pollution; damage to biodiversity; the potential for new allergens and toxins to be created; food security being placed in the hands of a few big corporations; economic risks to farmers, retailers and food producers; and damage to democratic traditions if the technology is imposed against the wishes of British people. Many of these are interrelated and interdependent. For example, if companies do not obey safety rules such as buffer zones[37], genetic pollution of wild species and organic crops may arise threatening biodiversity, the economic future of organic farmers and peoples' right to choice about what they eat.

These are questions which can only be informed to a very limited extent by small scale field trials with GM crops conducted on a case-by-case basis over the short term and under idealised conditions. The results cannot be extrapolated to the commercial jungle of the wider agricultural and natural environment without question and considerable caution. However, the scientific advisory system which has been established seems to have become culturally comfortable with just such an extrapolation, making hidden political, social and economic judgements in the interests of GM crops and foods. Whilst this may provide a convenient screen for politicians for a time, it contributes to the public's increasing lack of trust in British institutions as they are perceived as biased and unresponsive to public concerns. It is also, of course, bad science.

Members of ACRE and ACNFP have shown, in statements they have made, that they hold generally positive feelings towards GM crops. For example, when giving evidence at the House of Lords Select Committee on European Communities last year, Professor Bainbridge, the chair of ACNFP, pointed out:

> "I think at the end of the day we have to be minded about issues like industrial competitiveness and economic concerns. Even as an academic scientist you cannot be divorced from economics these days . . .."[38]

On ACRE there are industry representatives from Zeneca (Nigel Poole) and PPL Therapeutics (Ian Garner), companies both actively engaged in genetic engineering and profiting from it. The deputy chairman of ACRE (David Onions) is on the advisory board of PPL Therapeutics and another member, Tony Garland,

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[36] Report of the demonstration programme on food safety evaluation of genetically modified foods as a basis for market introduction. Ministry of Economic Affairs: The Hague, The Netherlands, 1998.

[37] 24 March 1999.

[38] The potential for this is very real. Earlier this year Monsanto was prosecuted for failing to observe buffer zones in an experimental trial with GM oilseed rape. Enforcing such controls when GM crops are used on a commercial scale may prove impossible.

was formerly a Glaxo-Wellcome employee. There is no balance from industry representatives of the wholefood, organic trade or even conventional farming industry.

A Friends of the Earth report also identified six members of ACRE who were connected with institutes that have been allowed by ACRE to conduct releases of GMOs[39] Julie Hill, the only member of ACRE from a public interest group has said that "*ACRE is the wrong group of people because the committee is short on ecologists . . .*" And that "*. . . it is valid to point out that often [ACRE members] come to the deliberations from a background of enthusiasm for the technology*"[40].

A predisposition to the technology is likely to lead to a more optimistic view of the risks involved which cannot be justified scientifically.

(iii) The Ability of the Current Systems to Respond to Rapid Scientific Developments

GeneWatch cannot think of any scientific developments in the arena of GM foods that should have demanded some kind of rapid emergency response by scientific advisors. Scientists and others working in the area should have been aware of issues such as cloning (debated extensively during discussions over the patenting directive in Europe throughout the mid-90s), knock-on effects of toxins in GM crops on beneficial insects (papers published as early as 1994 identified this issue), and potential for toxic effects of lectins (a very long-term question). That these issues become hotly contested is due to earlier lack of previous attention rather than lack of a mechanism to deal with them. This lack of serious attention again seems to reflect the optimistic attitude of regulators and scientific advisors arising from their positive views on the technology. The issues flair up because they are so at odds with more widely held societal concerns about the technology.

(iv) The Proposal for an Overarching Body to Consider all GM Food Issues

The recognition that there are many interconnecting issues involved in the assessment of GM crops and foods that is reflected in the proposal for an overarching body is very welcome. The crucial question is whether and under what circumstances such a body could improve the quality of decision making. It must not be seen as a mechanism for appeasing public opinion or mollifying public interest groups. It would only work if it had an active and productive role which, in turn, would only come from Government recognition that the quality of decisions could be improved through a broader input.

The conditions for a successful overarching body include:

- An established remit to identify and map out areas of debate which are relevant to GMOs. This should include current and emerging issues.
- No requirement to come to a consensus—the most valuable information for a decision maker is the scope and dimensions of an issue.
- A formal role to report to the Cabinet Office—as a transboundary issue, GMOs must move outside the confines of a particular department.
- An open and accountable system of appointment and operation.
- Proper financial provision for members to be able to undertake the work involved—this is critical for public interest groups to be able to participate fully. If support is not given to public interest groups, they will be unable to devote the time and make the commitment necessary. This may put them at considerable disadvantage to other members such as those from industry or academia who have secure incomes and provision for such work. Without financial provision, having lay members on such bodies may become tokenism.

However, GeneWatch believes that an "overarching body" must not be allowed to substitute for accountable, democratic systems of governance. There will remain decisions to be taken that are rightly the domain of our political representatives.

(v) The Capacity of the Government to be an "Intelligent Customer" for the Advice it Receives

This is a very interesting question and the answer depends upon whether the Government is able to recognise two crucial factors:

- that the framing of the question about the environmental and human safety of GM foods is crucial to the outcome.
- that "scientific" risk assessments always carry elements of uncertainty.

What is included in a risk assessment must reflect societie's concerns if it is to gain acceptance. This has been echoed in an influential recent report by the US National Research Council which emphasised the

[39] *Financial Times* 9 July 1998 "Environmentalists urge sackings at genetics body".
[40] Julie Hill. "Acres uncultivated" *The Guardian* 15 July 1998.

importance of this concept of "risk characterisation" in contrast to the more quantitative aspects of risk assessment. The NRC observed that[41]:

> "In addition to the biological and physical outcomes that are typically covered, decision makers and interested and affected parties often need to know about the significant economic costs and benefits of alternatives, secondary effects of hazard events, or the efficacy of alternative regulatory mechanisms".
>
> "A risk characterisation will fail to be useful if the underlying analysis addresses questions and issues that are different from those of concern to the decision makers and affected parties".

An appraisal process which excludes what are held by some constituencies to be important factors, may fail to secure the crucial property of public confidence. It follows from this that, by instilling a misleading impression of completeness, robustness or rigour, risk assessments based on such incomplete risk characterisation may leave regulators and business highly exposed to a subsequent backlash on the part of the excluded constituencies. This is exactly the situation with GM crops and foods in the UK at the moment. Likewise, the addition of "ethics" as a separable (and often final) "bolt on" stage in the process of regulatory appraisal may also often prove inadequate and misleading.

Judgements have to be made about what is relevant and included in an assessment, what importance is given to any findings and how uncertainty is characterised. Therefore important political, social, ethical and economic judgements are part of the final decision. To be intelligent receivers of advice, Government must be alert to the framing of the risk characterisation and the fundamentally uncertain nature of scientific knowledge.

26 March 1999

APPENDIX 33

Memorandum submitted by Dr Andrew Stirling, Fellow, SPRU (Science and Technology Policy Research), University of Sussex and Mr Robin Grove-White, Director, Centre for Study of Environmental Change, Lancaster University

1. This is a joint submission by Dr Andrew Stirling (AS) and Mr Robin Grove-White (RGW), reflecting recent work conducted respectively at SPRU (science and technology policy research), University of Sussex, and the Centre for the Study of Environmental Change (CSEC), Lancaster University, two of the country's leading independent research units on issues relating to applications of scientific advice and knowledge in contemporary environmental policy domains, including genetically modified (GM) crops and foods.

2. In conjunction with research conducted under the auspices of the Global Environmental Change Programme of the ESRC, both AS and RGW have led or contributed to a variety of recent investigations relevant to central issues in the Select Committee's current inquiry. These investigations include:

(i) A joint CSEC-Green Alliance ESRC-funded study of strengths and limitations of current official advisory oversight of GM crop releases (ESRC, 1996);

(ii) A major Unilever-sponsored qualitatitve research study (*Uncertain World: Genetically Modified Organisms, Food, and Public Attitudes in Britain*) analysing public concerns about emerging GM food-related developments, and their relationship to current regulatory norms (CSEC, 1997);

(iii) Co-opted membership (AS) of the Treasury—co-ordinated sub-group on safety assessment of the Government's Inter-Departmental Liaison Group on Risk Assessment (ILGRA, 1998);

(iv) Co-opted membership (RGW) of the on-going Royal Commission on Environmental Pollution Working Group on "GMs and Public Values" (see RCEP, 1999);

(v) An on-going Unilever-sponsored study (RGW) of the role and limitations of "public information" in regulating GM and other technological innovations(1999–);

(vi) An on-going Unilever-sponsored experiment (AS) in "multi-criteria mapping"—a way of taking transparent and systematic account both of science and public values in the regulatory appraisal of GM crops (1998–99);

(vii) Co-ordination (AS) of an EU-funded multi-disciplinary study of the implications of "science based regulation" and the "precautionary principle" for the regulation of technological risks including GM crops (1998–99); and

(viii) Joint research leadership (RGW) of an EU-funded five-nation study comparing public perceptions of agricultural biotechnology in Britain, France, Germany, Italy and Spain (1998–2000).

3. These various initiatives have built on the key finding in study (ii) above, that there are serious mismatches between (on the one hand) the scope and capacity of the present framework for regulatory appraisal of GM foods and crops, and (on the other) the kinds of "scientific" advice that may now be socially appropriate in this sphere.

[41] National Research Council (1996) Understanding risk: informing decisions in a democratic society. P C Stern & H V Fineberg (eds). National Academy: Washington DC.

4. Several of the recent projects (eg (iv)-(viii) above) have involved examination of, and experimentation with, ways in which these mismatches might be addressed.

5. In the Annex[42] to this submission, we offer more detailed observations on some of the structural limitations of the present system for the provision of scientific advice in the regulation of GM foods and crops. These are set out according to the specific issues highlighted by the Select Committee concerning "the adequacy and quality of scientific advice at present" and "the role and framework of advisory committees". We also suggest in the Annex criteria that might be adopted in seeking to improve the Government's currently under-resourced capacity to be an "intelligent customer" for the type of advice which it now requires in this sphere.

6. Summary of Key Contentions

The need to address gaps in the current advisory frameworks: Whilst the quality of the particular scientific advice reaching Ministers in relation to specific GM foods and crops may or may not be satisfactory in its own terms, the scope of that advice continues to embrace only a relatively restricted number of the issues of evident public significance. For instance, examination of the benefits envisaged for GM strategies remains entirely excluded from regulatory appraisal. Particular difficulties are posed by the one-at-a-time, product-by-product character of the assessments used by the key Ministerial Advisory Committees. The circumscribed basis for existing scientific advice and the way it is framed leave such Committees seriously under-equipped to provide the desired comprehensive, scientifically robust underpinning for regulatory decision making in this area. Some of the themes which are significantly under-addressed in the current system for the provision of scientific advice are precisely those emphasised in widespread public concerns (as clarified in study (ii) cited above). These include:

- the potential for indirect, cumulative and synergistic ecological and/or health effects arising from multiple cross-species GM crops and foods, over time;
- the full character of existing scientific ignorance and deep "uncertainty" and the likelihood or otherwise of major future GM-related "surprises";
- the appropriate weight to assign to different—and often countervailing—aspects of the risks posed by different agricultural strategies (such as human health, biodiversity loss, pesticide use and so on);
- the degree of authentic public control and international pluralism that might be desirable and possible in a WTO GM trading regime dominated by a small number of large companies; and
- the potential or otherwise for longer term future GM-related environmental and social feedbacks, in the event of widespread diffusion of the technologies in question.

(b) The need to broaden intellectual frameworks and be more attentive to social factors: Concerns over the intellectual framing of the current scientific advice system do not only concern the scope of individual scientific assessments. They also raise the prospect of complementing natural- with social-scientific expertise in a way which is likely to help strengthen the credibility of public policy in this area. It is not only recent academic studies such as those of SPRU and CSEC mentioned above which suggest this. Aiming in part at improving the degree of trust in the regulatory process, a series of official analyses by ILGRA (1998), RCEP (1998, 1999) and the US National Research Council (1996), have also identified a pressing need for inclusion within the scope of scientific assessments, of systematic consideration of legitimate social concerns about risks, uncertainties, and ignorance.

(c) The need to retrieve the consequences of recent government complacency: On the basis of our experience over the past three years, there are serious grounds for concern about the capacity or willingness of key arms of government to explore with appropriate effort and rigour the range of adjustments to present advisory practice that may now be needed. It is clear, for instance, that there has been a serious failure on the part of government to anticipate the recent public and media brouhahas over GM crops. It would be difficult not to relate this failure to a persistent complacency over the adequacy of prevailing arrangements for regulatory appraisal, despite earlier warnings to the contrary (eg Macrory (1997); studies (i) & (ii) above; Stirling (1998)).

(d) The need for new "social intelligence" experiments and methodologies: We and others have argued repeatedly (Royal Society (1998); studies (i) & (ii) above; Stirling (1998)) for the funding of new forms of experimental research with "listening exercises" and "participatory deliberation"—exploring ways of generating improved "social intelligence" with the potential to inform the framing of scientific and wider evaluations of GM developments and other contemporary "risk issues". The recommendation by the RCEP for a new over-arching body charged with attuning government to public values in a more energetic and interactive fashion than hitherto, is an example of a practical proposal in this regard. Recent SPRU and CSEC initiatives (para 2. above) have been seeking to assist in this direction, particularly the current Unilever-sponsored "multi-criteria mapping" exercise which offers one way of combining the benefits of public participation with the systematic discipline and transparency of more analytical appraisal methods. Similarly, the current OST consultation and other recent, more independent *ad hoc* "participatory" initiatives (building

[42] Page 245.

on the 1996 BBSCR-Science Museum GM Consensus Conference; for example, the recent joint "Citizen Foresight" initiative of the University of East London and Genetics Forum) represent positive, if still under-resourced and under-regarded, initiatives in broadly the same direction. However, our own recent direct experience has been that, with the exception of the RCEP, it is corners of industry (not least within companies like Unilever) that have begun to foster more genuine indepedence of thought and freedom to experiment. For Whitehall departments and agencies, by contrast, a central recent priority seems rather to have been a preoccupation with avoiding the undermining of established government GM policy trajectories.

7. In short, it is our view that current systems for the provision of scientific advice on issues raised by the pursuit of GM strategies in agriculture and food production are quite seriously circumscribed and flawed. There is a neglect of systematic attention to the effect of divergent interests and social values on the assumptions that frame the science and to contrasting perceptions and responses to uncertainty. The potential costs and wider consequences of these shortcomings hold strong implications for government policy and corporate strategies, as well as for wider public trust in the regulation of GM technologies. In this light, more effective provision for "participatory deliberation" and the gathering of "social intelligence" become matters not just of legitimacy, effectiveness and (often) expediency in regulation, but also a fundamental issue of analytical rigour. There is no shortage of candidates for practical techniques by means of which to elicit, explore, verify and so (potentially) address divergent public perspectives and thereby help remedy some of the shortcomings in existing regulatory appraisal. Some of these methods (such as consensus conferences, citizen's juries, focus groups and deliberative polls) are, to varying degrees, quite well-tested and increasingly established in certain other countries. To date, however, efforts at investigating and validating the available approaches in the UK have been made disproportionately by academic, non-governmental and some industry bodies. Given the scale of the stakes involved, substantive government initiatives in this regard seem to us now to be manifestly overdue.

29 March 1999

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Annex

The Adequacy and Quality of Scientific Advice at Present

A.1 Significant questions may be raised both over the adequacy and the quality of current systems for the provision of scientific advice on GM foods in the UK. In common with risk assessment in other technological fields, the picture given by any body of scientific advice on GM foods must necessarily be subject to an array of crucial "framing assumptions". These assumptions concern factors such as:

— the breadth of regulatory appraisal (those issues and policy options which are included and those which are excluded in analysis, for instance including factors such as comparisons between alternative farming practices or the consideration of indirect and synergistic ecological effects)

— the way individual aspects of risk are characterised and measured (eg the geographical scope and treatment of time horizons in appraisal, or assumptions over operating environments, working practices or regulatory compliance)

— the implicit priorities adopted in grouping together different aspects of risk in appraisal (eg health versus environmental effects, involuntary versus voluntary risks, risks to different groups of people)

— the treatment of deep uncertainties and "ignorance" (the potential for surprise—concerning not just the likelihoods of different outcomes, but the possibilitiy of entirely unforeseen effects).

A.2 The profound importance of such "framing assumptions" tends to be under-emphasised in narrow notions of "sound science" in regulatory appraisal. Under such views, the risks associated with policy options like GM foods are held in principle to be characterisable on a case by case basis in a definitive—even objective—fashion. The resulting risks are held to be readily expressed in the quantitative, discrete (and often highly precise) terms of probabilities and magnitudes. Although it is acknowledged to be difficult to achieve in practice, it is to this model of unitary objectivity that the present UK system of scientific advice on GM foods currently often effectively aspires.

A.3 Under a broader notion of scientific rigour, however, such notions of "sound science" appear to be simplistic, incomplete and even potentially counter-productive. In terms of the most fundamental tenets of probability theory, for instance, the concept of "risk" itself applies only under certain highly restricted circumstances. Probabilities are—by definition—quite simply inapplicable under conditions of strict uncertainty and ignorance such as those encountered in the appraisal of GM food. Likewise, the adding together of different magnitudes in risk assessment is a classical problem of comparing apples and pears. It has long been established from first principles in social choice and utility theory that there can be no single definitive way to aggregate such incommensurable factors in a plural democratic society such as that of the UK. Although individual assessments may appear highly precise and definitive, the uncomfortable reality is that the ostensibly "objective" procedures of risk assessment on which current scientific advice on GM foods in the UK is based may actually yield highly ambiguous results when the impacts of different possible framing assumptions are explored.

A.4 The business of deciding what is best from the point of view of society as a whole therefore cannot be reduced simply to a matter of "sound science" or "rational economics", nor determined simply by analysis. Any truly scientifically rigorous approach to the provision of policy advice must fully acknowledge the implications of these fundamental scientific realities. There is a double irony in attempts to assert the authority of a single unitary "objective" "sound scientific" picture of risks (such those associated with GM foods). First, by neglecting the scientific basis for the problems of ignorance and incommensurability, such efforts actually fall short of a truly scientific approach. Second, by purporting to achieve the unachievable, such scientistic hubris serves to help undermine trust and thus aggravate the very socio-political tensions which it is intended to circumvent.

A.5 The crucial point is that—with GM foods as with other risks—the choice of one framing assumption rather than another in risk assessment is often highly contingent and context dependent. Choices over what constitutes the most *reasonable* set of framing assumptions are a matter not primarily of scientific rationality but of intrinsically subjective value judgement. Different socio-political constituencies and interest groups will favour different—and equally legitimate—assumptions. The different sets of assumptions, in their turn, can exert a major influence on the resulting picture of the risks—affecting not just the absolute values but sometimes even the relative orderings of different options such as GM crops, conventional intensive agriculture and organic farming. In this light, it emerges that the systematic mapping of social values and priorities by the various available techniques for "participatory deliberation" and the gathering of "social intelligence" become a matter not just of the expediency, legitimacy and practical effectiveness of regulation, but also a fundamental issue of analytical rigour in appraisal.

A.6 To turn to the specific issues of "adequacy" and "quality" highlighted by the Select Committee, the implications of SPRU, CSEC and other research in this area are clear. Without systematic and transparent attention to the treatment of framing assumptions, the utility of scientific advice is seriously compromised. Taken on their own, then, the key parameters of risk assessment (namely probability estimates and damage magnitudes) must certainly be considered *inadequate*. In order to provide a more complete basis for policy advice, treatment of such factors must be complemented by robust, empirically-grounded information concerning the potential choices, priorities, methodological conventions and uncertainties associated with different stakeholders and wider public constituencies.

A.7 However, the difficulties with narrow notions of science in current policy advice on GM foods are a matter of "quality" as well as "adequacy". The reason is that the science and its framing assumptions are not separate and discrete. They are inextricably intertwined. It is therefore not enough simply that some consideration of "ethical issues" be "bolted on" as a subordinate or consequent activity following traditional risk assessment. The implications of research conducted by CSEC, SPRU and others is that it is a fundamental characteristic of a truly scientific approach to regulatory appraisal that account be taken right from the outset of the effects of divergent—but equally legitimate—ways of characterising risks. In short, the *quality* of scientific advice (as well as its *adequacy*) depends on the systematic, transparent and unconstrained exploration of the relationships between subjectivity in framing assumptions and the associated picture of relative risks.

The Role and Framework of Advisory Committees

A.8 Although they still remain under-appreciated in many areas of the risk debate—in particular that on GM foods—recognition of the difficulties with narrow conceptions of science in policy advice are far from new. These themes are well anticipated, for instance, in Chapter 5 of the 1992 report of the Royal Society. They are dealt with in some detail in the 1996 report of the US National Research Council (NRC) on *Understanding Risk*. It is for this reason that, as early as 1995, DETR guidance on risk assessment acknowledged that even the estimation of risks (the essentially scientific business of establishing probabilities and magnitudes) is intrinsically subjective in nature. The discussion was taken several significant steps forward by the Royal Commission on Environmental Pollution (RCEP) in their 1998 report on the setting of environmental standards. In the context of GM foods, the implications are further developed in the RCEP submission of February 1999 to the recent OST consultation.

A.9 Well-established though it is in some areas of the debate, emerging recognition of the difficulties of narrow notions of science remain almost entirely unaddressed in the formal system for the provision of scientific advice on issues such as GM foods in the UK. Here, the approach continues to be based on a model of expert consensus—the provision of a single ostensibly definitive "sound scientific" picture, based on essentially private deliberations by a committee of specialists such as ACRE or the ACNFP. With attention focusing almost exclusively on monolithic pronouncements of "safety" or "tolerability", the precise nature of the framing assumptions adopted by such expert committees remain tacit, and so effectively unacknowledged and unexplored. The degree to which the particular framing assumptions adopted in a given body of scientific advice actually reflect those extant in the wider debate over GM foods is not subject to any systematic examination. The extent to which the outcome of appraisal would differ with the adoption of different framing assumptions remains obscure.

A.10 The UK system of scientific advisory committees has yet to address the implications of the intrinsic subjectivity of framing assumptions in risk assessment which is now coming to be recognised by bodies such as the Royal Society, the NRC, the DETR and the RCEP (all cited above). The point is not that any set of framing assumptions is as good as any other. Only a small set of all logically possible assumptions will actually be acceptable or defensible in practice. The point is rather that, in any given context, more than one set of assumptions may be equally reasonable in appraisal. The adoption of any particular set of framing assumptions in risk assessment must therefore be justified. Since the framing assumptions are by their nature exogenous to the risk assessment itself, such justification cannot be undertaken in terms of "science" but must rather be assessed in terms of factors such as participatory deliberation, institutional legitimacy, democratic accountability and ethical acceptability.

A.11 In order for this to be achieved, the existing system for the elicitation of specialist scientific opinion needs to be augmented and complemented by a correspondingly systematic and robust process for the formulation and testing of framing assumptions. Here, it is not enough that a single lay member or "public interest" representative be admitted to serve on an expert committee. There seems little reason to believe that the particular interests and values of such an individual will offer any more reliable or complete a reflection of perspectives in the wider society than would those of the individual experts themselves. The need is rather for the systematic provision of auditable information concerning the full diversity of interests and values which are characteristic of the different public constituencies and other interested and affected parties.

A.12 There is no shortage of techniques and procedures by which such information might be gathered, interpreted and verified. Consensus conferences, citizen's juries, focus groups and deliberative polls are all relatively well established in the regulatory appraisal of technological risks in certain other industrialised countries (eg Renn *et al,* 1996; Durant and Joss, 1995). These and other techniques have all been tested on an experimental scale in the UK. Techniques such as multi-criteria appraisal and "sensitivity mapping" offer a way of combining quantitative and qualitative factors in appraisal, rendering more transparent the framing of scientific advice and providing an "audit trail" as robust as any in traditional risk assessment. Some of these approaches have been found in research at CSEC, SPRU and elsewhere to hold promise as a complement to the present UK system of advisory committees. It is only through methods such as these that we may hope to explore, construct, refine and validate the different ways of framing and interpreting scientific advice in the regulation of risks such as those of GM foods.

The Capacity of Government to be an "Intelligent Customer" for the Advice it Receives

A.13 It is part of the role of an "intelligent customer" clearly to specify and communicate the criteria which are to be applied in assessing the quality of the commodity in question. In this regard, a provisional set of simple quality criteria for the regulatory appraisal of GM food are emerging from the research conducted at CSEC, SPRU and elsewhere. These criteria subsume and go beyond those conventionally associated with the provision of science advice, because they explicitly address the inter-connections between the substance of this advice and the way it is framed, interpreted and articulated with wider regulatory decision making. As formulated in a recent SPRU report to the EU Forward Studies Unit, these criteria require:

— Broadening the scope of regulatory appraisal to address associated social benefits and include complex, synergistic, cumulative, additive and indirect effects.

— Conducting appraisal on a comparative rather than a case-by-case basis, including account of a variety of agricultural strategies, regulatory regimes and diverse mixtures of options.

— Acknowledging the intinsically subjective character of the assumptions adopted in the framing of scientific advice and formulate, selecting and defending accordingly those which are pursued.

— Maintaining a culture of humility and pluralism in the face of the many sources of uncertainty and ignorance in the appraisal of GM foods and other agricultural strategies.

— Complementing and informing scientific analysis with procedures for inclusive deliberation by stakeholders, such as consensus conferences citizen's juries, focus groups and deliberative polls.

— Experimenting with the potential for straightforward multi-criteria appraisal techniques as a way of taking account of relationships between science and value judgements.

— Expressing appraisal results not as single discrete numerical values, but using sensitivity analysis systematically to "map" the consequences of different value judgements and framing assumptions.

— Conforming with principles of transparency and precaution in the conduct of appraisal and making provision for extended peer review of the results.

— Providing for iteration, reflexivity and open-endedness in the interactions between sustained scientific monitoring, continued analysis and inclusive deliberation in appraisal.

— Upholding the primacy of institutional legitimacy and political accountability in the final justification of regulatory decisions.

APPENDIX 34

Memorandum submitted by the Institute of Science in Society (ISIS)

1. Introduction

1.1 The Institute of Science in Society is an independent, non-profit research and educational organisation dedicated to developing and promoting socially responsible science, sustainable science, science for the public good and the integration of science in society. The Board of Directors and Founding Members include: Professor Nick Furbank, Professor Brian Goodwin, Dr Mae-Wan Ho, Ms Angela Ryan and Professor Peter Saunders.

1.2 Summary: We consider the scientific advice at present to be inadequate in terms of scope and balance, and insufficiently up-to-date. The precautionary principle does not appear to be part of the framework of advisory committees. The current system lacks the ability to respond to rapid scientific developments. We strongly support an overarching food committee which considers food safety, health, environmental, social and ethical impacts together; and which is also able to make proactive recommendations on research and development. It is necessary for the Government to be an "intelligent customer" for the advice it receives. Two specific issues we consider to be very important are discussed at greater length: the membership of the advisory committee and the nature of the evidence that is to be placed before it. The committee should include scientists who are not associated either directly or indirectly with the gene biotechnology industry, and the scientific evidence placed before the committee should, as far as possible, be publicly available. Under no circumstances should a new process or product be authorised if the committee has been denied access to evidence that it considered important.

2. Response to the Specific Points Raised

2.1 We consider the scientific advice at present to be inadequate. The scientists on the committees are chosen largely from the ranks of those who are in one way or another predisposed in favour of gene biotechnology. The advice given often does not take the most recent scientific findings sufficiently into account. Furthermore, there has been no attempt, on the part of the Government, to obtain advice directly from the wider scientific community.

2.2 It is the Government that must decide on the framework within which the advisory committees should operate, and ministers must both accept this responsibility and be conscious of what it implies. The UK can choose to operate under the precautionary principle, as we strongly believe it should, so that before a new process or product is authorised it must be shown to be safe, or at least to have a level of risk acceptable, given the need or likely benefits. Alternatively, it could follow the World Trade Organisation and other "free trade" agreements and adopt what we might call the inverse precautionary principle, according to which any proposed new process or product must be authorised unless proven unsafe. The WTO decision preventing the EU from banning the import of products from cattle treated with rBST is an example. A NAFTA ruling last year requiring Canada to accept a new additive in petrol is another. As it is for the Government, not the advisory committees, to decide which principle is to apply, and ministers and civil servants must understand the issues well enough to make rational, responsible decisions.

2.3 The current system does not appear to have the ability to respond to rapid scientific developments. This reflects the lack of any independent advisory body whose remit it is to monitor and keep up with new

developments, and the failure of decision-makers to obtain advice directly from the wider scientific community.

2.4 We strongly support the proposal for an overarching food committee which considers food safety, health, environmental, social and ethical impacts together. The issues are complex, many of them highly technical, and the field is developing rapidly and will have major impacts on all aspects of civil society. Such a body would also be expected to keep abreast of scientific developments and to make proactive recommendations on which lines of research and development should be encouraged or avoided.

2.5 While we do not expect ministers and civil servants to be experts in molecular biology, it would be useful if at least a few people in the relevant ministries were. Nevertheless, because it is the Government, not the advisory committee, that is ultimately responsible, ministers must be able to understand what the committee has concluded, and on what grounds. They should make it their business to know, at least, in general terms, how genetic engineering is carried out, and how it differs from traditional breeding, and about phenomena such as horizontal gene transfer, on which genetic engineering is based. If they are going to approve products in which an expression such as "substantial equivalence" appears, they should ask what precisely the term means, and be able to understand the answer they are given. While the advisory committee will make recommendations in individual cases, it is the Government that must inform itself and the committee by commissioning research, and it should draw on a wide range of expertise. In Norway, for example, the relevant Government agency, the Directorate for Nature Management, has commissioned an independent scientist directly to produce a report on the ecological risks from horizontal gene transfer associated with the use of naked DNA in research, production and gene therapy. (A copy of the summary of this report has been supplied to the Clerk of the Committee).

3. Membership of the Advisory Committee

3.1 We recognise that there is bound to be a problem in choosing the members of an advisory committee. Inevitably, most of those with the necessary expertise will be involved in the activity that is to be regulated. In the case of genetically modified foods, many of the best qualified scientists are directly associated with companies in the food or chemical industry. Others are working in research institutes or universities that rely wholly or partly on funding from those industries. Members of the committee are required to declare their interest or leave the room when an application from a company with which they are associated is being discussed. This may well prevent any one company from going outside what is considered acceptable by the majority of those working in the industry. It does not, however, guarantee adequate regulation of the industry as a whole.

3.2 To achieve that, the committees must include qualified scientists who are not connected, directly or indirectly, with the industry. Genetic engineering is a rapidly evolving subject, and it is not easy for an outsider to be aware of the latest developments. Only someone with up-to-date knowledge can properly judge the evidence that is put before the committee. Only such a person will have the background to know which statements are plausible and which are not, and be able to ask appropriate questions in case of doubt. A year or two ago, faced with the statement that DNA is completely broken down in the gut, how many lay people would have thought to doubt that and ask for the evidence?

3.3 There is a place for lay people on regulatory bodies, but they are not a substitute for scientists completely independent of the industry. Lay people cannot make a proper contribution if they are obliged to accept as given that which they are told by scientists linked with the industry. Without the full, if frequently uncertain, scientific picture, they can do little more than put an ethical gloss on what industry has to say.

3.4 We cannot give examples of what has happened within the present committes as we do not have access to records of the discussions. Nevertheless, it is instructive to look at the booklet *Ethics, Morality and Crop Biotechnology,* published in 1996 by the BBSRC. It is difficult to see this as anything other than an apologia for gene biotechnology. In particular, it ends with a number of loaded questions, such as "Should the prime responsibility of scientists be to reduce risks to the absolute minimum, *regardless of* [our italics] the anticipated benefits?" The authors also state, "The history of science has proved to be highly unpredictable, and there can be no guarantee that "playing safe" by abandoning research and development in crop biotechnology will not deny us a technique which may *prevent* [italics in original] an environmental disaster in fifty years time." This is an example of the "inverse precautionary principle" mentioned above.

3.5 At present, both government and industrial funding in molecular genetics is heavily biased towards research connected in some way with the development of commercial products or techniques. As a result, most scientists who are sufficiently active and up-to-date are, directly or indirectly, involved in those development. Far fewer are carrying out research that might throw light on the hazards. The Research Councils should give such research a much higher priority than at present.

3.6 Not only would the results of such research be of interest to regulatory bodies, by supporting it, the Research Councils would be helping to maintain a pool of scientists who could make valuable contributions to advisory committees. It is not just that they would be independent of industry, though that is indeed important. They would also approach issues from different points of view and with different, relevant experiences, complementing those of scientists involved in exploiting the technology.

4. Scientific Evidence

4.1 The view has been expressed—in connection with evidence suggesting that the genetic engineering process itself is hazardous—that only results which have been peer-reviewed and published in learned journals should be taken into account. Yet the results of much of the work carried out by industry, including experiments designed to test the safety of new products, have been neither peer-reviewed nor published, but have nevertheless been accepted by the advisory committees in approvals of the field trials and commercial releases. It is very important for the Government to ensure that scientific advisory committees base their recommendations on careful scrutiny of all relevant evidence on both sides of the debate, whether published or not.

4.2 Confidentiality can be invoked as a means of avoiding proper scrutiny. Companies often do, however, have legitimate concerns about commercially sensitive information. In such cases, evidence should be provided to members of the advisory committee under conditions of strict confidentiality. Under no circumstances should a new process or product be authorised if the committee has been denied access to material it considered important. Except where the committee agrees that confidentiality is appropriate, all evidence should be made publicly available so that as many people as possible are able to comment on it. In this way, expertise beyond that possessed by the members of the committee can be brought into service.

28 March 1999

APPENDIX 35

Memorandum submitted by the Institution of Professionals, Managers and Specialists

Introduction

1. The Institution of Professionals, Managers and Specialists (IPMS) is a trade union representing 78,000 scientific, technical and specialist staff in the Civil Service, research councils, other public sector bodies and an increasing number of private sector companies. IPMS submitted evidence to the Committee's inquiry in May 1998, but, in relation to the current case study, would wish to point out that our members are directly involved in a range of biotechnology-related activities. Institutes of the Biotechnology and Biological Sciences Research Council (BBSRC) and of the Natural Environment Research Council (NERC) undertake basic research in this area and are represented on the relevant regulatory bodies. The Scottish Agricultural College is also engaged in research involving trials of GM crops. From the commercial end, IPMS has members in Monsanto via the latter's acquisition of Plant Breeding International. Regulatory functions are undertaken by IPMS members in the Health and Safety Executive and the Ministry of Agriculture, Fisheries and Food and members in environmental bodies, like English Nature, are involved in the regulatory process in an advisory capacity.

2. This submission focuses on the five issues identified by the Committee.

Adequacy and Quality of Scientific Advice

3. The scientific dimension of general decision-making within government has always been weak in a predominantly "generalist" civil service and is getting weaker. The separation of a unified senior civil service from specialists located mostly in agencies, with separate pay and grading structures, makes vertical and diagonal movement into more generalist posts even more difficult than before. There are no longer service-wide career management or trawling systems. The provision of specific scientific advice is becoming more difficult and expensive to access because of the increasingly commercial and contractural nature of the transactions between separate policy "customers" in departments and "contractors" either in separate next steps agencies or privatised.

4. The recently announced Government study into the commercialisation of research in public sector research establishments is of concern in this regard. As outlined in paragraph 15, as well as having implications for the capacity of the Government to act as an intelligent customer for scientific research, it raises potential conflicts of interest for staff. This comes at a time when members report that all institutes are already under considerable pressure to take on more commercially funded research and that the ceiling for industrial funding has been progressively raised. As Monsanto is a major commissioner of research into genetic modification, perceptions of the independence of government research are called into doubt, as was the case when the Medical Research Council was seen to accept funding from the tobacco industry. IPMS is aware that government scientists have been given a low credibility rating by the public who now apparently trust private companies more, partly as a result of the BSE crisis. We believe that this reflects a misunderstanding of the role of government scientists *vis-à-vis* politicians. It is to be hoped that the establishment of the Food Standards Agency (FSA) will help to rebuild confidence. However, it is vital that all experts advising government should declare their interests and that all advice should be open and subject to scrutiny by others.

5. There is also a need for much greater co-ordination of science policy and advice across departments as well as within them. The Office of Science and Technology is small and weak, and both the Chief Scientific

Adviser and Science Minister's influence on other departments needs substantial strengthening. The externalisation of scientific staff, whether by the establishment of agencies or outright privatisation, makes it more difficult to ensure that science is integral to departmental policy making. It also increases dependence on external experts, who are unlikely to be as politically astute in relation to the workings of government as internal scientists. The degree to which scientists are represented in decision making processes should be carefully monitored and steps taken to strengthen their presence in policy making, both general and scientific.

Role and Framework of Advisory Committees

6. IPMS has some concerns about the operation of existing advisory committees:

— Long term effects on biodiversity are not adequately considered—This is a concern shared by both the National Biotechnology Conference and the House of Lords Select Committee on the European Communities, which noted in their recent report on "EC Regulation of Genetic Modification in Agriculture" that current risk assessment does not adequately address indirect and cumulative effects of genetic modification. Similarly, the Parliamentary Office of Science and Technology (POST) report on GMOs concluded that "general issues such as the role of (GM) crops in agriculture and the effects on the rural. . . have no obvious forum for their resolution". So, although the case by case approach to the regulation of GMOs must be continued, IPMS supports the House of Lords Committee's recommendation that risk assessment procedures and the regulatory system should consider wider ecological effects and the changes that are likely to arise as further variants of major crops become available. These should include assessment of potential environmental benefits of GMOs.

— There is potential for confusion over Ministerial responsibilities—This is manifested by the split in reporting responsibilities of the Advisory Committee on Genetic Modification (ACGM) (to MAFF) and Advisory Committee on Releases to the Environment (ACRE) (to DETR). A recent example of the problems created by this fragmentation is that of the release of herbicide-tolerant oilseed rape. ACRE considered the risks to human health and the environment including the transfer of herbicide-tolerant genes to wild relatives but was not able to make a judgement about the change in herbicide use and agronomic practice which might follow the release of the crop and have effects in the environment. In fact, a review of whether herbicide use will rise or fall following the introduction of GM crops is being conducted separately by the Pesticides Safety Directorate. A greater emphasis on co-ordination would be welcome and, in fact, is critical for commissioning research where, in addition to MAFF and DETR, the Department of Health also has an interest in novel foods.

— Ethical and social issues are not fully considered—These wider issues are beyond the remit of both the Advisory Committee on Genetic Modification (ACGM) and the Advisory Committee on Releases to the Environment (ACRE). The proposed revisions to EU Directive 90/220/EEC on voluntary release into the environment of GMOs should, if implemented, give greater impetus to consideration of issues of public concern, including ethics. The recent assurance by the Environment Minister that ethical implications of biotechnology will be taken into account in responding to public concerns is to be welcomed. IPMS agrees strongly with the view expressed by Professor Sir Tom Blundell at a recent meeting of the Parliamentary Scientific Committee that, whilst stringent science must provide the basis for dispassionate and systematic analysis, standards must also be sensitive to public values and based on continuous public consultation and involvement. In practical terms this may mean giving greater emphasis to systematic collection of data on moral and ethical issues.

7. The objective should be a simpler system, with clearer lines through to Ministers. One option would be to establish an overview committee, chaired by the Chief Scientific Adviser, to report direct to the Cabinet on all matters raised by the regulatory committees. This would provide a central focus and greater transparency. The interface with practices and procedures in other EU Member States should also be considered.

8. IPMS notes that the Government is considering holding more meetings of advisory committees in public. Whilst in principle greater openness is to be welcomed and should have a positive role in building confidence in the regulatory process, it is debatable whether this will be best achieved by opening up meetings of technical advisory committees to the public. Genuine public participation in a wider stakeholder forum, as suggested by the Government, may provide a more representative and meaningful basis for communication and consultation (see paragraph 13 below).

Ability of the Current System to Respond to Rapid Scientific Developments

9. It is evident that the regulatory framework is already running to keep up with the developments in biotechnology. One of the major problems is that the technology is developing more rapidly than the ability to comprehend some of its implications, and certainly more rapidly than some of the underpinning research in ecology and environmental science can be completed. Often, ecological research lies on the critical path of

the risk assessment for GM releases, and understanding of natural systems sufficiently imperfect to produce an element of risk attached to most releases.

10. It is important that the regulatory framework is seen to respond in a timely manner to these developments, yet the danger is that further rapid progress will add to complexities in the present framework. A move to fewer committees with a wider remit and broader membership would assist a more effective response to new situations. This would also provide an opportunity to open up transfer of information to the public, but there must be no short cuts in scientific assessment and decisions must also be taken in the context of the wider European framework and standards.

Value of the Proposed Overarching Body to Advise on and Oversee all Genetically Modified Food Issues

11. All the evidence is that public confidence in GM products is diminishing. For example, a recent opinion survey for Monsanto showed that over half of respondents were negative about foods with GM ingredients, up from 38 per cent in 1997, and that just 12 per cent had positive views. At European level, a recent Eurobarometer survey showed that whilst a majority of Europeans thought that various applications of biotechnology would benefit society, the applications perceived to be most risky and least useful were those used in food production. Perception that there is a lack of consumer choice in this matter plays an important part in the overall lack of confidence.

12. Whilst IPMS deplores criminal acts of sabotage, there is no doubt that they do highlight fears and uncertainties as well as distrust of commercial motivation. Having an advisory system that is seen to be open, robust and fully independent from the industry provides no guarantee that confidence will increase, nor should it. However, the lesson of the BSE crisis is that the public will not trust either official guidance or the technology itself unless these criteria are fulfilled.

13. IPMS therefore welcomes the proposal by the Environment Minister to establish a stakeholder forum with wider terms of reference. It is important that the views of NGOs including trade unions are heard within government circles. In addition, the stakeholder forum could usefully become a focus for broader consultation, for example through mechanisms such as consensus conferences which could help in promoting understanding of basic concepts of risk, probability and scientific uncertainty as well as raising awareness on specific issues and contributing to policy decisions. However, even with a wider stakeholder forum, there should continue to be a strong technical input to GMO advice and regulation.

Capacity of Government to be an "Intelligent Customer" for the Advice it Receives

14. As already mentioned, most scientists in government are to be found in next steps agencies except where they have already been privatised. It is just as important for these scientists to remain close to decision making as it is for those internal to central departments. This is the most cost effective way of providing scientific services and advice because it facilitates flexibility and speed of co-ordinated response and leaves the majority of staff in close contact with ongoing research, whether they are doing it themselves or at the end of a telephone line from those who do. As far as genetically modified foods are concerned this closeness of contact will be important, for example, for the agencies of the Ministry of Agriculture, Fisheries and Food that are to remain ouside the remit of the FSA. Equally important will be the development of a close relationship between the FSA and the public sector research establishments from which it commissions research. The BBSRC, for instance, will be a key research provider. It would be sensible to therefore make a provision for FSA representation on BBSRC's Council and to establish a reciprocal arrangement for BBSRC representation within the FSA.

15. However, as previously indicated, pressures to commercialise can create conflicts of interest which need to be addressed seriously. Experience in North America, where there has been strong pressure from those who invest in spin-out companies to lock in the inventors, is instructive. Federal and State governments have developed policies to expose and avoid conflicts of interest for employees, to which research institutes must conform as a condition of receiving public funding. For example, the National Science Foundation requires that any faculty member with a shareholding of $5,000 dollars or an equity stake of 5 per cent in a spin-out company must disclose an interest, which then has to be reviewed to determine whether it is material. If so, grant funding may only be awarded if steps are taken to separate the researcher from his/her commercial interest. This approach deliberately seeks to force researchers into a choice between the spin-out company and their public research establishment.

16. Although the UK currently lags some way behind, all the indications are that it, like the Netherlands and France, is on a parallel course. The results of John Baker's study could accelerate the process of commercialisation by PSRE's. At the same time, codes of conduct established by the Nolan Committee into Standards in Public Life are beginning to have a wider effect. Serious thought therefore needs to be given by government to establish clear guidelines on disclosure of interest backed by active policies of annual disclosure, clear and transparent procedures for review of disclosures, and clear criteria for decisions on whether interests are material. In similar vein, processes will be needed to deal with institutional conflicts of interest. It certainly cannot be assumed that the pressure for commercialisation can be sustained either

without detriment to the relationship with government customers or to public perceptions on the independence of research advice.

30 March 1999

APPENDIX 36

Memorandum submitted by The Royal Society of Edinburgh

1. The Royal Society of Edinburgh is pleased to respond to the Select Committee's request for comments on Genetically Modified (GM) Foods in connection with its Inquiry into the Scientific Advisory System. The RSE is Scotland's premier learned society, comprising Fellows elected on the basis of their distinction, from the full range of academic disciplines, and from industry, commerce and the professions. This response has been compiled with the assistance of a number of Fellows with many years experience in biotechnology or working in scientific advisory roles.

2. The issues surrounding GM foods include: the development of foods, environmental containment, medical effects on human health, the monitoring and tracing of products (eg by public analysts), as well as the effects of genetic modification on plant—and animal—precursors of "food", on agricultural systems, and on animal health through feedstuffs. It will, therefore, be important not to compartmentalise the subject, as such compartmentalisation may lie at the root of some of the currently perceived problems regarding genetic modification in general. Not taking a holistic view may well expose the Government to criticism but, perhaps more importantly, can prevent solutions to real or perceived problems being reached.

3. The specific areas of consideration are addressed below:

(i) The Adequacy and Quality of Scientific Advice at Present

4. While the thoroughness and quality of the scientific advice available on this issue is good, GM foods come almost entirely into the category where scientific evidence is, as yet, partial and constantly under review. In terms of environmental impacts, it is worth noting that as genetic modifications are the basis for evolutionary change, we are unlikely to know the full extent of any consequences of escapes into the environment until time on an evolutionary time-scale has passed. The scientific evidence is, therefore, likely to remain incomplete for the foreseeable future. When scientific advice identifies areas of doubt or ignorance, it is important that decisions of policy makers reflect this and, in matters of public safety, err reasonably and in proportion on the side of caution. It is worth noting that much of the research on genetic modification of foods is in the hands of commercial organisations or subject to private sector support.

5. For the non-scientist, however, the range of acronyms and the complexities of the terminologies employed in biotechnology (as in other scientific, legal, financial, and sociological disciplines) present significant barriers. Given the necessity of retaining public confidence in the knowledge-based industries of the future it is necessary to ensure that the public has ready access to information. However, this must be presented in a fashion that the public can understand, and which is seen to be independent. The intended Food Standards Agency could be in a position to help with this.

(ii) The Role and Framework of Advisory Committees

6. There is currently a wide array of expertise and Committees to advise Government Departments. This advice should, however, avoid being compartmentalised by Department, and merely reactive to requests for licensing of processes, crops or foods, or R&D funding. What is needed is more pro-active activity on advances in biotechnology and genetic modification and their potential implications for people, animals, plants and the environment, in order to inform the Government of the matters on which it ought to seek advice. Further, to a large extent the present public alarm has arisen because of a failure to prepare the public for the new technology. In ensuring the quality and speed of advice to Government, it is equally important to ensure that the advice and available information are communicated to the public. There would be merit, therefore, in the development of public communications plans for those major areas of science that are likely to arise as areas of public concern.

7. Existing committees, such as the Advisory Committee on Novel Foods and Processes (ACNFP), or the proposed Advisory Committee on Animal Feedingstuffs (ACAF), must analyse the experimental data supporting the efficacy and safety of specific GM food products on a case-by-case basis. Much of this information would need to be provided by the commercial sponsor of the GM crop or food product, who in view of the current situation in the UK and EU, may be more motivated to have the results of mandatory compositional analyses, allergenicity testing and rodent feeding trials made public in some encoded or anonymous way.

8. Committees should include expertise at an international level in the areas being investigated, and they should have proper administrative support to enable them to function quickly. Provision should also be made to second experts to these committees as and when a response is required to a new scientific development outwith the expertise of the standing committee members.

(iii) The Ability of the Current System to Respond to Rapid Scientific Developments

9. There would be merit in a complete and co-ordinated register of all those with relevant professional knowledge in higher education institutions and in public sector research establishments, able to advise and provide specific detailed responses to issues raised by particular cases being reviewed by Government advisory committees. If existing advisory committees comprise the appropriate experts, and have sufficient back-up and support, then the current system will be able to cope with the rapid pace of scientific development.

10. It should be noted that the matters under consideration are, by their very nature, novel with little or no case history to which to turn. It is, therefore often necessary to proceed with due caution. Rapid responses may not always be possible if risks to the public and the environment are to be properly assessed. In terms of the flexibility of the present framework it should also be recognised that the UK approach has to fit into a European regulatory framework.

(iv) To What Extent is there Value in the Proposal for an Overarching Body to Advise on and Oversee all Genetically Modified Food Issues

11. The complexity and professional quality of the existing UK Advisory Committees are more than adequate to address all the issues presently being aired. Provided the guidelines and boundaries of the existing committees are well-defined, and that adequate cross-communication takes place, we see no value in establishing yet another body to advise on, or to oversee, GM food issues as a specific subset of the issues addressed by the 16 existing biotechnology advisory committees.

12. It is important, however, that there should be an overall committee to discuss and co-ordinate the work of the biotechnology advisory committees. While the Advisory Committee on Releases into the Environment (ACRE), ACAF and the Food Advisory Committee (FAC) have interests in GM foods, and advise on the issues these novel materials present, part of a central committee's function would be to ensure that aspects of GM foods did not fall between existing committees. Such a committee could also bring together the findings of different committees, initiate a more pro-active approach to identifying the emerging issues and anticipating the questions Government may have to address, and consider the wider ethical, moral, social and economic issues.

13. There should also be some interaction between the committee regulatory process and science funding activity. It can be envisaged that developments in agriculture will impinge on others in medicine, and vice versa. Specific research or development might be needed to harmonise the work in these disciplines, and to identify and fill gaps in knowledge and understanding of the issues concerned.

14. If the UK cannot resolve the safety issues without delaying all potential developments, we are likely to lose out in the biotechnology stakes and, in the longer term, will not be able to resist the pervasiveness of the ultimate products, as genetically modified soya has demonstrated.

(v) The Capacity of Government to be an "Intelligent Customer" for the Advice it Receives

15. The Government's capacity to be an "intelligent customer" in this matter is difficult. In a democratic society it is recognised that political judgements can override other considerations. It is essential, however, to accept that many real questions do not have yes/no answers, either in the present state of knowledge or at all.

16. With regard to GM foods, there are difficulties in being an intelligent customer because sound scientific evidence on environmental effects is unlikely to be available for a long time, while financial resources are likely to remain constrained. In addition, long-term politico-economic considerations are difficult within our 5-year election cycle.

Additional Information

In responding to this inquiry the Society would like to draw attention to the following Royal Society of Edinburgh publications which are of relevance to this subject: *The Scientific Advisory System* (June 1998); *Review of the Framework for Overseeing Developments in Biotechnology* (February 1999) and *The Food Standards Agency: Draft Legislation* (March 1999). Copies of this response and the above publications are available from the Research Officer, Dr Marc Rands (email: mrands@rse.org.uk).

31 March 1999

APPENDIX 37

Memorandum submitted by the Institute of Biology, the Association of Applied Biologists, the British Crop Protection Council, the British Ecological Society, the British Grassland Society, the British Phycological Society, the Institute of Horticulture, the Nutrition Society and the Systematics Association

1. The Institute of Biology is pleased to respond to the above consultation with a number of its Affiliated Societies, namely: the Association of Applied Biologists, the British Crop Protection Council, the British Ecological Society, the British Grassland Society, the British Phycological Society, the Institute of Horticulture, the Nutrition Society, and the Systematics Association. The Institute of Biology is the independent, charitable body charged by Royal Charter to present UK biology and biologists. Its Affiliated Societies are bodies whose members have considerable special life science expertise. Together these bodies can provide considered responses to those issues of the day that in some way relate to the various biological sciences.

Summary

2. The principal points of this response include:

(a) the need for adequate time to formulate advice is important;

(b) existing Government guidelines on the way consultations are conducted are welcome;

(c) despite finite resources the scientific professional bodies and learned societies are good sources of advice;

(d) the use of commercial bodies to conduct Government, its Departments, and Agencies, consultations is not recommended;

(e) advice may vary so it is important that this and the reasons for this are made clear to its recipients;

(f) research is required to underpin advice and researchers need to be given enough time so that they can contribute to the formulation of advice (they have other pressures);

(g) Advisory Committees play a useful role but their remits need to be very clearly defined;

(h) developments in the media and public mind can develop faster than scientific research can provide answers;

(i) there should be clear scientific justification for any moratorium for the commerical planting of Genetically Modified (GM) crops.

General

Our previous response to the first part of this "advice" enquiry is still relevant

3. We refer the Select Committee to the response made by this Institute together with a number of its Affiliates to the first part of scientific advice enquiry last year. We believe that the points made then are still applicable, and if anything are now more relevant.

Our response on GM crops to the Nuffield Council on Bioethics may be of interest

4. The Institute and some of its Affiliated Societies have already responded to the Nuffield Council on Bioethics consultation on Genetically Modified (GM) Crops. We are pleased to attach this response for information[43].

Select Committee's specific questions

THE ADEQUACY AND QUALITY OF SCIENTIFIC ADVICE AT PRESENT

Chartered bodies and assemblages of learned societies are quality sources of scientific advice

5. We have not been privy to the full range of scientific advice. However, we consider the advice that has been produced by a number of scientists and which has subsequently gone through some approval mechanism to be of considerable value. As such, the views of Chartered scientific bodies (such as the Institute of Biology and Royal Society of Chemistry) and assemblages of learned societies (such as the UK National Committee for Microbiology) should be particularly welcome. This is not to say that the views of individuals should be discounted but Government should be aware of the expertise these individuals as a guide to the likely quality of the advice offered.

[43] The Committee is not printing the Institute's appended evidence to the Nuffield Council on Bioethics on GM Crops. This may be viewed on www.iob.org.

Incorporating approval/review mechanisms within advice formulation procedures takes time

6. Enhancing the quality of scientific advice involves identifying experts, liaising with appropriate bodies, synthesising drafts, soliciting comment and, in the instance of institutional responses, obtaining appropriate approval. However, while enhancing the quality of advice, this all takes time. Conversely short time-scales greatly impact on the quality of scientific responses.

Government's guidance on consultation time allowances, weighting and follow-up information is satisfactory

7. We welcome the guidance from the Cabinet Office (June, 1999)[5] and in particular the advice on the time that those consulted should be allowed and the provision of follow-up information. Specifically:

(a) "Eight weeks for replies should generally be the minimum for all consultation exercises, but whenever possible more should be allowed. Where less than eight weeks is allowed, the document should specify why a longer response time could not have been given (for example pre-determined statutory periods for consultation, threats to health . . .)."

(b) "The issuing department, agency or other body should make allowances for holiday periods and other potential timing difficulties."

(c) "The issuing department, agency or other body should decide at the time of consultation how to deal with requests for the deadline for comments to be extended, and how to acknowledge responses".

The time allowed for consultations is sometimes short

8. As indicated in our previous response on scientific advice, the time for consultation is sometimes short. The current Genetic Modification example is that of the consultation being conducted by the Environmental Audit Committee for which three weeks has been given. Short time-scales greatly affect the provision of quality scientific advice. We understand that others such as the UK National Committee for Microbiology will be raising concerns over time-scales.

"Adequacy" relates to the users' needs and not science

9. "The adequacy of scientific advice at present" depends on the recipient's needs; in this case the prime user is the Government with secondary users being those with an interest in this topic and the advice Government receives. Consequently, depending on the users' needs, some advice may not be as "satisfactory" as might be wished. With regard to GM foods, advice might be to ensure that GM food crops are not grown within a certain distance of their unmodified counterparts to prevent cross-breeding. Such practices will not be welcome by some (such as those to whom this represents an extra cost or burden to a prospective market) but to others the advice may not go far enough—there is indeed a lobby that does not like GM food crop field trials at all. In short, there may be an expectation for the scientific advice to provide a firm answer welcome by all. That it cannot always do so might be considered by some as inadequate to meet users' needs.

Science cannot always provide a single, satisfactory answer with certainty

10. Lack of a single, precise answer "satisfactory" to all is especially true of advice relating to "cutting edge" scientific issues. By definition such areas are new and unfamiliar and so tend to be sources of controversy. This does not mean that the "quality" of the scientific advice *per se* is poor. Nor does it mean that the advice might not change as new discoveries are made. Advice therefore needs to be qualified in recognition of this. It is for this reason that we have the "precautionary principle".

Scientists with different expertise may emphasise advice differently

11. The quality of the advice may be influenced unintentionally, in that certain aspects may be emphasised by some scientists compared to others with differing expertise and involvement. Regarding GM foods, it is not unlikely for those scientists working in the GM industry to stress the benefits, whereas those working in conservation or biomedicine might place more weight on ecological or possible toxicological concerns. Neither may be providing incorrent advice *per se*. For these reasons the Royal Chartered bodies can provide a broader base for advice which might therefore be of more utitlity. The Institute itself recognises the value of assemblages of learned societies.

Recognition of where scientific opinions differ is necessary for advice to be transparent

12. Even within a group of scientists, let alone a whole profession, opinion may differ. Advice sought on areas of new science is less likely to be understood and so may become a source of controversy. Where the evidence is not complete it should be acknowledged in the advice so that the advice is seen to be transparent. Failure for advice to be transparent, in terms of starting areas of genuine debate as well as source, can undermine the confidence in such advice.

Research is required to underpin advice, occasionally research is threatened by concerns over the technological application of science and not necessarily the science itself

13. It sould be noted that frequently it is not the science *per se* that is being questioned but "technology"; the way the science is applied. One of the concerns identified by the Institute's bioethics of GM crops response (*cf* appendix)[44] is that the scientific research on GM crops needs to continue even if there are currently concerns as to the commercial use of the technology. The more information that is available the less likely that there will be concerns over the technology. Scientific advice in turn depends on the understanding gained from research. However, if technological concerns unnecessarily impede scientific research then the quality of the scientific advice being sought may be comprised and its scope limited.

The Role and Framework of Advisory Committees

The quality of Advisory Committees can sometimes be checked through further consultation with the scientific community, but their generic role is useful

14. The quality of the advice from the formal Advisory Committees can, if needs be, be checked against consultations with the scientific community at large whose professional bodies may frequently be able to solicit views from alternative independent experts. However, authoritative advice on the very latest scientific developments can only usually be given by the few people working on that specific cutting edge. This often means that the advice formally given through the Government's Advisory Committees comes from those associated with the same people as those chosen to represent the academic community. Consequently the formal Advisory Committees properly fulfil a useful generic role.

Individual Advisory Committees may need to have their specific roles more carefully defined

15. While the overall role of Advisory Committees is of considerable value, there may be a case for individual Advisory Committees to have their specific roles more carefully defined. For example, relating to GM crops, in November the Advisory Committee on Releases to the Environment (ACRE) had its remit extended from considering direct and indirect environmental impacts to including impacts on biodiversity. However, many life scientists would consider an impact on biodiversity to be an environmental impact and so be surprised that likely biodiversity impacts were not already being considered.

The Ability of the Current System to Respond to Rapid Scientific Advancement

Media-driven and political developments are frequently faster than scientific ones

16. The advice system in the main is able to respond to rapid scientific advancement (as opposed to responding rapidly to scientific developments). However, there are difficulties in responding to rapid media and political developments as these can take place at a much faster rate. Media-driven and political developments usually require a speedy resolution. The early identification of likely issues of concern is required. The Institute has recognised this as a problem and is considering the possibility of producing discussion and/or information papers of topics of likely future concern. However, so as to channel resources to maximum effect it would appreciate guidance as to the likely topics it might address.

Professional and learned bodies have limited resources and UK scientists, already highly productive, have pressures, other than providing scientific advice, competing for their time

17. The ability to respond to rapid advancements by independent scientists and professional and learned bodies is also compromised by resource limitations. The number of requests received by the Institute of Biology far exceeds its ability to respond. However, not only are the professional science and learned bodies voluntary, and frequently charitable, but scientists themselves have considerable demands on their time. UK scientists can in a number of ways (in terms of papers produced and their impact per £ spend on research) be considered to be far more productive than scientists from other countries. This, though, means that public sector university-based scientists have little time for competing activities such as providing advice. Such activities are referred to as "scholarship activities" by the Higher Education Funding Council. The Institute and a number of its Affiliated Societies have already expressed concern that such activities (which can enhance a researcher's abilities) are not being fully taken into account by the Research Assessment Exercise. If Assessments were to include such activities then it is likely that obtaining good scientific advice and encouraging constructive scientific debate on issues of the day would be facilitated.

[44] Not printed.

Industrial scientists may require employer compensation if they are to be released to provide advice

18. If the advice of industrial scientists is sought then some mechanism for compensating the employer will be required if the scientist is to be given the time to provide the best advice.

The use of commercial bodies to conduct consultations is not recommended and can slow and filter responses

19. Contracting-out of consultation servicing by Government Departments to commerical organisations adds another tier to the consultation process, so slowing the Government's ability to receive advice and adding a filter. Futhermore the use of commerical organisations is less preferable when there are already independent voluntary bodies that may be approached whose Royal Charter provides a constitutional *raison d'être* to determine the views of the profession they represent. An example of where a commercial body was employed relating to Genetic Modification is that of the 1996 DoE consultation on the wider implications of genetically modifying organisms (DoE contract No 1/5/63.)

To What Extent is there Value in the Proposal for an Over-arching Body to Advise on and Oversee all GM Food Issues?

Opinion is divided, but on balance there is little call for such a body

20. Opinion is divided as to the overall value of this proposal, but the balance of the views we have received suggests there is little call for such a body. The principal reasons for such a body would be if the current system was either incomplete or that there were conflicts in the remits of its constituent parts. A transparent review would need to be conducted to ascertain this.

The Capacity of Government to be an Intelligent Customer for the Advice it Receives

MPs with scientific training, POST, and the S&T Select Committees from both Houses can help Government be an intelligent customer

21. There is understandable difficulty for those Members of Parliament without scientific training to comprehend scientific reasoning, its benefits and the limitations of its application. However, those who do have such training should be placed in those Ministries that involve science. The contributions of the Parliamentary Office of Science and Technology, the Select Committees of both Houses, and indeed the Parliamentary and Scientific Committee do much to assist the Government to be an intelligent customer. Government should value the output from these bodies.

Semantics can confound the capacity to be an intelligent customer

22. Interpreting wording, especially where it has been carefully chosen, needs to be done carefully. When the Institute and a number of its Affiliates responded to the Nuffield Council on Bioethics on G M Crops it said that UK and EU development controls "are in theory pragmatically sound" (*cf* appendix paragraph 12). By using the word "theory" we tried to convey the need to ensure that practice must follow theory and not be decoupled from it. By including the word "pragmatically" we were alluding to the fact that stricter controls might engender less risk but they would not be pragmatic. What was not said was that "the controls are sound" as neither this Institute nor the Affiliated Societies authoring the responses are involved in monitoring the controls. Lack of precision of meaning can also be confusing. For instance, with regard to GM food one big issue in the public's mind is whether GM food is "safe"? But what does "safe" mean? Some may take "safe" as to mean *no risk*, while others that it means *small and minimal risk*. (Paragraph 15 above is illustrative of semantic confusion with regard to GM crops.)

Other Issues

Length of commercial planting moratorium needs careful consideration

23. We are aware of advice being given to Government calling for a moratorium on the *commercial* planting of GM crops for three years while the potential ecological impacts are assessed. The length of the moratorium needs careful consideration. We wish to make the following points:

(a) this research might take longer than three years to conduct, and further time will be needed for assessment.

(b) that not all GM crops pose a significant ecological risk (such as those with no wild relatives in the UK or whose chemical management is the same as non-GM crops). There is therefore no GM-related, nor crop management-related ecological reason for low-risk crops to have to endure as long a moratorium as those posing a potentially greater risk.

Transparency for consumers—labelling

24. We are aware of scientific advice being given (including by this Institute and some of its Affiliates (*cf* appendix, paragraph 18))[45] calling for complete transparency of GM crops in the food chain. This Institute qualified this recommendation by stating that "wherever possible" there should be transparency as to the presence of GM foods in the food chain. However, we would like to emphasise that there are limits to detection as well as the possibility for modified crops to enter early in the human food chain through animal feeds, especially through imported foods. We suspect that this issue will become of increasing importance to the public and advise that early disclosure of the fact and honesty regarding limitations is required for the public debate.

25. Should the Committee require further information relating to this consultation response then in the first instance it should contact: Jonathan Cowie, Institute of Biology, 20-22 Queensberry Place, London SW7 2DZ. In line with Government policy on openness we propose that this consultation response be made public. A list of all IoB responses in recent years, together with the test of the main ones, is available on the Institute web site *www.iob.org*

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2. Institute of Biology, the Association of Applied Biology, the British Crop Protection Council, the British Ecological Society, the British Electrophoresis Society, the British Grassland Society and the Institute of Horticulture (1988) *Genetically Modified Crops: The Social and Ethical Issues.* Institute of Biology: London.

3. Service First Unit (1998) *How to conduct written consultation exercises.* EX30 1998–1999. Cabinet Office: London.

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30 March 1999

APPENDIX 38

Memorandum submitted by Independent Television News

1. Independent Television News (ITN) is the major commercial supplier of broadcast news in the United Kingdom. It supplies ITV, Channel 4 and Channel 5 with their national and international news services. It supplies, via Independent Radio News, more than 200 independent radio stations. It operates Euronews, the pan-European news channel currently available in more than 90 million homes across Europe. ITN's reports are also seen around the world on its World News for Public Television, which is available in 38 per cent of homes in the United States. In addition, ITN supplies its reports to NBC in the United States and CNN world-wide. ITN also operates a number of websites and new services for digital television.

2. ITN has regularly covered the issues surrounding genetically modified foods on all of its news programmes. Editorial decisions are taken by the editor and news editors of the different services. ITN's overall editorial priorities are set and monitored by the Editor-in-Chief.

3. The diversity and complexity of the issues is reflected in the fact that a number of our specialist journalists have reported on different aspects of the controversy—our health correspondents, science editors, political correspondents and consumer affairs correspondents.

4. Main themes have so far included:

— the move by supermarkets and fast food outlets against GM products;

— local governments taking GM products off menus in schools;

— research showing the extent of GM ingredients in widely available products;

[45] Not printed.

— debate amongst scientists beginning the controversial research by Professor Pusztai on the effect of GM potatoes on rats, and the subsequent row about the scientific basis of these findings;

— Lord Sainsbury's involvement in a company which was involved in GM development, and his alleged conflict of interests;

— the Prime Minister's view that he would be happy to eat GM food;

— House of Lords' report that GM foods offer more benefits than drawbacks.

5. We also reported the Monsanto Court Case at Caistor Magistrates' Court.

6. At various times in the last few months, our correspondents have also appeared live on our programmes to discuss the latest developments at greater length.

7. In addition to this news reporting, we have devoted a number of extended special reports to the subject. We have looked at the experience of genetically modified food in other countries—such as the United States and Canada.

8. For ITV2, we have devoted a half hour edition of "Who, What, Why" (ITN's news explanation programme) to the subject. This featured a four minute video report on the issues raised, a definition of what qualifies as "genetically modified", and a discussion about the implications to both the consumer and the scientific community.

9. ITN's overall approach is that the scientific, political and consumer issues raised by genetically modified food are newsworthy, complex and controversial. ITN does not take any particular editorial line on the rights and wrongs of the various arguments. ITN's role is to provide impartial reporting reflecting all sides of the current debate.

31 March 1999

APPENDIX 39

Memorandum submitted by the Royal Society for the Protection of Birds

1. Introduction

1.1 The RSPB is mainly concerned with the possible indirect effects of GM crops on biodiversity, including the potential effects of changes to farming practice that may result from their introduction. Much of the wildlife of arable land has already suffered dramatic declines in the past 25 years. The decline of farmland birds has been particularly well documented and in some cases can be shown to be the result of agricultural intensification or changes in farm practice. The RSPB is concerned that the introduction of GM crops could continue and accelerate those trends and lead to even greater biodiversity loss.

2. Declines in Farmland Biodiversity

2.1 The Government has committed itself to conserving the population of 19 bird species which appear on the UK Biodiversity Action Plan (BAP). Of these, however, several have suffered declines of between 40 and 85 per cent in the past 25 years.

DECLINING BREEDING BIRD POPULATION TRENDS 1972–1996 FROM THE BTO/JNCC COMMON BIRDS CENSUS

species	*% decline*	*species*	*% decline*
grey partridge	−78	tree sparrow	−76
turtle dove	−85	linnet	−40
skylark	−75	reed bunting	−40
song thrush	−66	corn bunting	−74
spotted flycatcher	−78		

2.2 Farmland mammal species, such as brown hare and the pipistrelle bat have also undergone declines and appear in the UK BAP. Likewise, there have been serious declines in both numbers and diversity of insects on arable land. The Game Conservancy Trust recorded a 4.2 per cent decline per annum in 700 species of cereal arthropods between 1972 and 1990, and nearly 50 per cent of species of wild bee are considered to be under threat. Species of insects, including bees, moths and ground beetles associated with arable land feature in the UK BAP.

2.3 Plants of arable land have also dramatically declined in the past 40 years. Indeed a few species, such as corncockle and thoro-wax, are no longer found in the wild in the UK. The plant composition of arable land has also changed with annual grass plants, such as blackgrass and sterile brome, becoming more common over the past 20–30 years, and broad-leaved annuals declining.

3. The RSPB's concerns about GM crops

3.1 The RSPB is concerned about two aspects of genetically modified (GM) crops:

3.1.1 The impact of the GM crops on wildlife and the wider environment:

(a) the insecticide in insect resistant crops may kill non-target insect species, thus breaking down the wildlife food chain;

(b) gene transfer may take place between GM crops and related native species, producing hybrids which could damage wildlife habitats by displacing other plant species; alternatively, traits such as insect resistance transferred into wild plant species could lead to damage to ecosystems;

(c) GM crops might become agricultural weeds themselves and invade other wildlife habitats.

Examples (b) and (c) will take time to manifest themselves in the environment but, once established, may be impossible to rectify.

3.1.2 The impact of the use of GM crops on wildlife and the wider environment:

(In this respect GM crops are not dramatically different from other technologies used in farming, such as pesticides or ploughs.)

(a) use of broad-spectrum herbicides on herbicide-tolerant (HT) crops could reduce weed populations and disrupt the wildlife food chain;

(b) crop resistance to pests and diseases may lead to changes to cropping patterns and loss of rotations (the greater the variety of crops in the rotation the greater the variety of weeds and insects and therefore birds);

(c) novel traits inserted into crops may allow them to be grown in previously uncropped areas which may be important for wildlife (for example, uplands or estuaries).

Examples (b) and (c) are longer term possibilities.

3.2 The RSPB is calling for:

(a) The current regulatory process to be updated, as it does not adequately assess the impacts of GM crops on wildlife and the environment (particularly 3.1.2 (a) (b) and (c) listed above).

(b) A moratorium on the commercial use of genetically modified crops until the Government's field-scale trials looking into the impacts of herbicide-tolerant crops on wildlife are complete.

(c) All future crops to be tested for their impacts on wildlife and the environment before commercial release is considered. Any crops that have an adverse effect on wildlife should be banned from use in the UK.

3.3 The RSPB's position on genetically modified crops is very similar to that of English Nature. We have read and listened to the response to this inquiry from English Nature[46] and support the points that English Nature have made.

4. The Role and Framework of Advisory Committees

4.1 The RSPB agrees with all the points raised by English Nature (EN) on this issue. The RSPB supports the changes to widen the remit of ACRE. Our position on genetic modification of crops is that the Government should be concerned not just about the impact of the genetically modified crop itself, but also about the impact of using the crop in the countryside. The RSPB sits on the sub-committee of ACRE which is considering these wider issues.

4.2 We agree with English Nature's point (3.6 & 3.7) regarding statutory regulation and monitoring of GM crop management systems. At the time that ACRE proposed a voluntary code (3.7) to prevent risks of, for example, hybridisation, there was little understanding or acknowledgement of the wider impacts that GM crops may have on the environment and biodiversity. In the light of a better understanding of these impacts, and the fact that ACRE now considers them, we stress that GM crops should not be regulated any differently from pesticides.

4.3 The statutory regulations relating to GM crops could partly be enforced through "cross-compliance," proposals for which are currently under discussion as part of the reform of the CAP. Cross-compliance could require farmers to adhere to specific general conditions of practice in order to qualify for compensation payments.

5. The Adequacy and Quality of Scientific Advice

5.1 The RSPB stresses the need for further research into the wider impacts of GM crops on wildlife (points 4.1, 4.2 and 4.3 in EN's response). In 4.3 EN raises the prospect of crops tolerant to different climatic and soil conditions. The potential use of such crops raises issues which have not been widely considered, in spite

[46] HC 286–iii.

of their concern to the RSPB. Many upland areas, wetlands and estuaries are highly important for wildlife; if these areas were opened up for cultivation it could have disastrous consequences for the wildlife that exists there.

5.2 Many of the companies promoting GM technology talk of the ability to grow new industrial crops that could, for example, contain vaccines, or yield new fibres or materials. We would be concerned that the pressure to find new areas to grow crops of this kind may put severe pressure on fast disappearing wildlife habitats and would stress the need to research these issues further before proceeding.

5.3 Finally, we would particularly support the establishment of an over-arching body to provide advice on non-human biotechnology, as proposed by EN, and the Royal Society.

1 April 1999

APPENDIX 40

Memorandum submitted by the Natural Environment Research Council

INTRODUCTION

1. The Natural Environment Research Council (NERC) is the lead UK-wide organisation for basic, strategic and applied research and training across the spectrum of the environmental sciences. NERC's purpose is to support scientific research, survey and monitoring at universities and through its own Centres and Surveys: the British Antarctic Survey (BAS), the British Geological Survey (BGS), the Centre for Coastal and Marine Sciences (CCMS), the Centre for Ecology and Hydrology (CEH) and the Southampton Oceanography Centre (SOC—a joint venture with the University of Southampton). Research related to genetic modification is both undertaken at institutes within CEH and supported by NERC at universities. NERC's experience of the operation of the scientific advisory system is mainly in the area of the release of genetically modified (GM) crops.

2. This response draws on input provided by the Institute of Virology and Environmental Microbiology (IVEM) and the Institute of Terrestrial Ecology (ITE) (both part of CEH) and comments from NERC Council members. Our evidence is structured around the five points identified by the Committee; additional points are made under separate headings at the end of the memorandum.

MAIN COMMENTS

Adequacy and quality of scientific advice

3. Contact between the Department of the Environment, Transport and the Regions (whose Biotechnology Unit provides the secretariat for the Advisory Committee on Releases to the Environment (ACRE)) and NERC institutes is good. NERC scientists are connected to the advisory system via individual membership of advisory committees (see paragraph 19) and by consultation as technical witnesses and by commissioned research. Much of the science underpinning current UK regulations on risk assessment has been provided by NERC-funded scientists. Advice from NERC scientists at the ITE has formed the basis of:

(i) a classification of crops according to their likelihood of hybridisation with wild relatives. This has been used to categorise risk assessment protocols for different crops;

(ii) development of the above classification to lead to fast-tracking certain crop/construction combinations; and

(iii) a reassessment of the first (1994) consent for commercial release of a crop in the UK (the PGS hybrid oilseed rape).

4. Many of these scientists are also involved in the advisory system at a European and wider international level, for instance in helping to define the scope for harmonisation of risk assessment approaches and international trade. This has involved visits to China under EU auspices and Australia with USDA/OECD.

5. The process by which Government obtains and uses scientific advice is an issue of increasing public and media interest. NERC supports the principles recently set out by the Government's Chief Scientific Adviser for the provision of scientific advice to Government (The Use of Scientific Advice in Policy Making, March 1997):

(i) the process of gathering, assessing and reporting scientific advice should be open, transparent and consultative;

(ii) it must be based on the best scientific expertise and evidence;

(iii) advice must also highlight scientific uncertainties or divergencies in scientific opinion and knowledge.

Rôle and framework of advisory committees

6. We are not aware of any significant overlaps between advisory committees. In any case, provided communication is effective between secretariats, overlaps may be a strength.

7. The system for providing advice to Government is already transparent for ACRE. Indeed, industry has argued that it is too transparent at times. The exact locations of GM R&D trials are published; ACRE's minutes are published on the Internet/WWW within 15 days; members' interests are declared; some reports which ACRE receives are made public; and all releases are placed on the Public Register. It is difficult to see how the process could be made more transparent without either breaking commercial confidence or holding meetings in public.

8. Some have suggested that greater representation of environmental/NGO stakeholders should be included on the advisory committees. It may be most appropriate to seek democratically elected representatives of the people, such as Members of Parliament, rather than self-elected quasi-independent individuals to complement technical experts. Although the Advisory Committee on Genetic Modification (ACGM) is a little different from ACRE, each of the existing committees offer "technical" judgement on technical data and accept that trade and political realities are outside their competence. In our experience, the environmental stakeholders do have adequate influence. Indeed, elements in the agri-biotech business would say that UK plc is disadvantaged and suffers financially because of the influence currently exerted by environmental stakeholders.

9. EU legislation is expected increasingly to take on an ethical dimension and NERC supports the principles of bringing ethical and social issues into the formal regulatory process in some way. However, it is difficult to see how the expert advisory committees can do this. At present the coverage is patchy. Ethical issues are considered by the Advisory Committee on Novel Foods and Processes (ACNFP), for example, but not by ACRE although ACRE has appointed an independent social scientist.

10. There may be room to simplify the current system, though the need for technical advice will remain. We suspect that other countries in the EU may have more simplified structures, but they may also have biotechnology industries less diverse than those in the UK.

Response of the current system to rapid scientific developments

11. The systems applied by the Health and Safety Commission, and by the other regulatory and advisory bodies that we have encountered, are flexible and responsive. One of the major problems is that the technology is developing more rapidly than our ability to comprehend some of its implications, and certainly more rapidly than some of the underpinning research in ecology and environmental science can be completed. Where our understanding of natural systems is imperfect an element of risk will always exist.

Value in an overarching advisory body

12. The restricted remit of the advisory committees (such as ACRE and ACNFP) means that the framework for crop biotechnology is fragmented. Recently the Royal Society has called for an over-arching body to pull together the limited remits of the existing committees and take a more strategic view.

13. The recent release of herbicide-tolerant oilseed rape provides a good example of the weaknesses of current arrangements. ACRE assessed the risks to human health and the environment, including the transfer of the herbicide-tolerance genes to wild relatives. However, it was not able, or qualified, to make a judgement about the change in herbicide use and agronomic practice which might follow the release of the crop. Filling such knowledge gaps is probably best done by an over-arching body to ensure that there are overlaps in responsibility. Environmental Stakeholder Forums (ESF) are very valuable for many issues, however, they tend to achieve compromise positions rather than getting to the heart of the issue. Alternatives include cross-membership by the chairpersons of the relevant advisory committees and a body working in parallel on judgements about changes in herbicide use and agronomic practice.

Government's capacity to be an "intelligent customer"

14. From a scientific perspective most government departments maintain a close working relationship with the Research Councils and Science Base. NERC, for example, has concordat agreements with a number of departments, including: DETR, MAFF, DTI, the Scottish Office and Health Departments. Regular meetings involving scientists and departmental officials are arranged to brief both the department and NERC on scientific and policy issues of mutual interest.

OTHER COMMENTS

Public confidence

15. A vocal section of the public does not have confidence in the systems currently in place. It is also evident that the wider issue of public interest is not represented on the advisory committees. It is unlikely that many even know, or care, about the existing systems. The problems are largely about people's perceptions of the problem, their moral, ethical and religious unease, and the fact that for whatever reason they feel unable to trust experts. Other sections of the public have confidence in the quality, value and independence of advisory committees but less confidence in the political executive or in departmental positions where commercial interests confict with scientific views. The perceived MAFF position at the outset of the debacle over BSE is likely to have a durable negative impact on public perceptions. If the public values are not known or understood, and generally they are not, then they should be sought.

16. NERC's experts in this field are all actively involved in communicating their science to the lay public as well as to government, decision makers and other scientists. It is important that researchers are trained in communication skills, although explaining science in more detail will not necessarily engender public confidence.

17. Many people do not accept that risk is acceptable where the risks are unknown or the understanding of them is imperfect. There is genuine concern over the impact of GMO releases on ecosystems and the wider environment. These are issues which do have to be acknowledged and addressed.

18. It should also be recognised that the public has particular perceptions in respect of GMOs because it is aware of the "large American corporation" status of the companies trying to establish GMOs in the UK. Transnational corporations may engender particular dislike in the public mind for a variety of reasons, again something which scientists need to be mindful of, even if they do not wish to become involved in the debate.

NERC Involvement with the advisory system

19. The following members of NERC Council and senior staff are actively involved in the advisory system:

- Professor J E Beringer (Bristol University and Member of NERC Council)—Chairman of ACRE and Member of ACGM;
- Professor T M Roberts (Director of ITE and Designate Director of CEH)—Member of ACGM;
- Professor A J Gray (ITE)—Member of ACRE;
- Dr J I Cooper (IVEM)—Member of the Technical Sub-committee of ACGM.

March 1999

APPENDIX 41

Letter to the Committee Specialist from Professor Janet Bainbridge, Chair of the Advisory Committee on Novel Foods and Processes

Thank you for your letter of 19 April 1999 (see below) and reference to the two statements that I made.

In the first instance the comment made in my written answer to the Commons Committee was very specific and referred to the fact that in its decision-making, ACNFP is charged with providing the very best scientific advice, independent of commercial pressures, with the major consideration being the protection of public health. Hence, we do not at any time debate or discuss the effects our decisions might have on the commercial performance of the company making the submission.

However, in the second statement to the Lord's Select Committee on European communities, I believe I was making a more general generic point . . . this is that today scientists do have to be aware of the applications and commercial potential of their research and clearly in its deliberations the ACNFP is aware of this—indeed we do ask for data relating to scale of use of a novel food to enable us to evaluate likely potential exposure. Hence, we are not divorced from economic reality. However, we do not let out concerns for "UK plc" affect our decision making.

I hope that this clarifies the apparent dichotomy and reassures you that I was not being contradictory in my assertions.

Please do not hesitate to contact me if you require further clarification.

21 April 1999

Letter to Professor Bainbridge from the Committee Specialist

I have been asked to follow up on a point that you raised in your supplementary note to the Committee regarding GM food.

You stated that: *"the Committee is independent of commercial interest and does not see it as its remit to address issues such as the effect on of its decisions upon industrial competitiveness".*

This contrasts, at least in tone, with what you said to the Lords Select Committee on European Communities, concerning the arguments for a moratorium on cultivating GM crops:

> *"I think at the end of the day we have to be minded about issues like industrial competitiveness and economic concerns. Even as an academic scientist you cannot be divorced from economics these days . . . "*

Please could you clarify how, if you *"have to be minded about issues like industrial competitiveness and economic concerns"* you cannot see it as your remit *"to address issues such as the effect of its decisions upon industrial competitiveness".* Please may I have your reply by 26 April 1999?

19 April 1999

APPENDIX 42

Memorandum submitted by the Royal Society

INTRODUCTION

The House of Commons Science and Technology Committee launched an inquiry in February 1999 requesting comments on the current advisory framework for overseeing developments in genetically modified (GM) foods. The Royal Society welcomes the opportunity to comment and would like to stress the importance of providing sound scientific advice to policy makers.

The Society has already produced statements on genetically modified plants for food use (September 1998), biotechnology regulation in the UK (February 1999) and the scientific advisory system (June 1998). This document draws on recommendations already made in these publications. It covers the adequacy of the current advisory system and its ability to respond to scientific developments, transparency of scientific advice to Government and the proposal for an over-arching body. The response has been endorsed by the Council of the Society, and was prepared by a group chaired by Professor Brian Heap FRS (Foreign Secretary and Vice-President, Royal Society). The other members were Professor Ted Cocking FRS (University of Nottingham), Professor Don Grierson (University of Nottingham), Dr Terry Rabbitts FRS (Cambridge University), Professor Chris Leaver FRS (Oxford University) and Dr Rebecca Bowden (Secretary).

It is particularly important to take account of public values, and how these are formed, at all stages in any process of setting standards, as was outlined in the report of the Royal Commission on Environmental Pollution, published in 1998. Biotechnology has many potential applications to food production and agricultural practice and as a result it may also have immense industrial potential. Nevertheless, it is necessary to have adequate regulatory procedures in place to ensure all aspects of the technology are addressed.

The main issues that the society recommends be addressed by Government in order to improve the current advisory framework are as follows:

1. A presumption that scientific advice to Government will be made publicly available unless it is demonstrably against the national interest to do so;
2. Use of an overarching body, to which specialist advisory committees would report, to take a broad overview of developments and concerns related to biotechnology;
3. Increased use of *ad hoc* working parties to enable greater flexibility and rapid adaptation to scientific advances and to provide advice on specific issues of concern.

In the remainder of the document the Society lists its responses to the specific questions raised in the enquiry.

1. *The adequacy and quality of scientific advice at present*

The specialist advisory committees have a major role to play in providing a very high standard of expert advice to the policy makers on many complex issues. They represent the primary committees for the provision of an advisory system which was worked satisfactorily for the limited number of GM products submitted for marketing to date, but we have concerns about wider ecological implications.

The Society has already stated that the present system of regulation and advisory committees is inadequate in the face of likely future developments in biotechnology. We have recommended the formation of an overarching body to monitor wider issues (see question 4), in addition to an extension of the remits of relevant advisory committees. Such an overarching body should also monitor the membership of advisory committees to ensure adequate representation of environmental and consumer issues at all stages of the regulatory process. It is also important to take into account public values at all stages of the process, which necessitates

a means of determining such values. We recommend that there is an obligation on those seeking advice to consult widely in order to obtain a suitable breadth of knowledge.

Nevertheless, there are currently several overlaps in the advisory system, most notably between those advising on applications to market different GM products such as foods, feeds and medicinal products. There is a great potential for repetition and overlap unless there is strict top-down co-ordination of the regulatory process.

Matters are further confused by the existence of separate legislation for different types of products containing GMOs, and the proposal for further vertical legislation such as that governing GM seeds. Any such overlaps would be easier to identify if there were an overarching body monitoring the development of governmental policy on biotechnology as a whole.

2. *The role and framework of advisory committees*

Regarding the provision of scientific advice on GMOs to policy makers, the current use of a number of specialised advisory committees could be more efficiently co-ordinated if the Chairmen of such committees had an official forum in which to discuss concerns raised by their committees with respect to individual applications. It is also important for such issues to be reported to any overarching body responsible for monitoring developments as a whole. This would be possible if advisory committee Chairmen reported to such a body. It is equally important for the overarching body to have a means of communicating any concerns to the relevant advisory committees so that they may take action. The overarching body will also need to include consumer and environmental representatives, to ensure a suitable breadth of knowledge to monitor wider issues and long term developments. Such a body could then give advice to the Ministerial committee set up to monitor Government policy in biotechnology. If the committee were able to advise on cross-departmental issues then they could co-ordinate both the funding of biotechnology research and the regulation of the end-products of such research.

In addition, the current system of advisory committees could be simplified in the ways set out in sections 1 and 3 by removing overlaps in advisory committee remits and ensuring that there is the ability to co-opt experts or form working groups to enable rapid adaptation to scientific progress.

We welcome indications that the current Government is seeking to conduct its affairs more openly and support the approach set out by the Chief Scientific Advisor in "The use of scientific advice in policy making" regarding transparency. We strongly endorse the recommendation that there should be a presumption that scientific advice to Government will be made openly available, unless it is demonstrably against the national interest to do so.

We also welcome moves by the Advisory Committee on Novel Foods and Processes (ACNFP) and the Advisory Committee on Releases to the Environment (ACRE) to increase transparency in the regulatory system by the publication of agenda and minutes, and ACNFP's initiative to convene open meetings. We recommend that other advisory committees involved in the regulation of biotechnology, such as those advising on pesticides, consider such measures.

3. *The ability of the current system to respond to rapid scientific developments*

In addition to the areas of concern mentioned in 4, there is a degree of discrepancy in both membership and remit of the advisory committees. For example, the Advisory Committee on Novel Foods and Processes (ACNFP) currently has a member to provide advice on consumer issues, whereas the Advisory Committee on Release to the Environment (ACRE) does not. Also, members are occasionally common to more than one non-departmental public body. Whilst this has obvious advantages for the coordination of advice (eg membership of both ACNFP and ACRE), it has the disadvantage of limiting the number of independent advisors and hence narrowing the breadth of expertise available. We recommend increased use of co-opted members of advisory committees on an *ad hoc* basis, with individuals appointed on a personal basis to provide advice on specific issues, which would allow greater flexibility to respond to new scientific developments. In addition, advisory committees should make use of *ad hoc* working groups reporting to the main committee on specific issues of concern. We also recommend that membership of advisory committees is limited to a fixed term, perhaps three years, which will increase both flexibility and transparency.

We also recommend the consultation of independent bodies of international reputation and widespread consultation for specific purposes such as determining the degree of public confidence in the current regulatory framework.

4. *To what extent there is value in the proposal for an overarching body to advise on and oversee all genetically modified food issues*

Although genetic modification and the release of GMOs are tightly regulated in the UK, concerns have been expressed that there is no overarching body (as distinct from the primary specialist advisory committees), to monitor the impact of GM crops on agronomic practices or to look at the cumulative effects of such crops, since applications are reviewed on a case by cases basis. In 1994 the Biotechnology and

Biological Sciences Research Council (BBSRC) held a Consensus Conference on plant biotechnology at which a cross-section of lay persons considered the implications of these technologies. We agree with the recommendation of this panel that the regulatory authorities should address the wider issues surrounding the introduction of GM commodity crops by putting in place a monitoring mechanism or overarching organisation (as set out in our recent publication *Genetically Modified Plants for Food Use*).

We welcome recent moves by the Government to establish a Ministerial committee to oversee biotechnology. It is likely that such a committee will provide vital co-ordination of policy across departments. However, it will also be necessary to ensure that there is some mechanism for taking a broad, well informed overview of developments and concerns.

The reliance on a case by case approach in obtaining expert advice for policy makers may result in a lack of analysis of the overall impact of the technology on agriculture and the environment, and of the long-term effects of GMOs. In particular, the following points are not adequately covered by the current advisory committee system:

- review of enforcement mechanisms for current regulations;
- review of mechanisms by which GM crop plants could be monitored in the environment and recommendations for long-term monitoring of impact on ecosystems;
- review of current guidelines for isolation of certified seed crops and high erucic acid oilseed rape and provision of recommendations regarding isolation of specific GM crops or concern and possible statutory provisions;
- review of available methods for minimising gene transfer to crops and recommendations regarding further research;
- consideration of possible positive and negative effects of insect tolerant crops on the ecosystem and provision of guidelines for growth of such crops and recommendations for further research, as applicable;
- consideration of current guidelines for growth of GM and non-GM herbicide tolerant crops and the potential for statutory measures;
- regular review of advisory committee membership;
- analysis of the current regulations, with particular attention to consideration of whether allergenicity and toxicity of GM food receives adequate consideration;
- applications for herbicide use on a crop should be considered in conjunction with applications for release of herbicide tolerant crops. There should also be a mechanism by which the long-term impact of such crops on agricultural practices could be monitored;
- consideration of the potential effects of GM crops in comparison with the effects of current agricultural practices in general on ecosystems and the environment as a whole.

We therefore recommend that these issues be covered via extending the remit of the appropriate advisory committees. In addition, an overarching body is needed to have an ongoing role in monitoring the wider issues associated with the development of biotechnology in agriculture and food production. Such a body should consider those of the above issues that cannot be considered by individual advisory committees for practical reasons. In addition, the Food Standards Agency and Ministerial Committee will have an overseeing role to play on some aspects of biotechnology. We acknowledge that many of the concerns raised cannot be addressed without the information gained from long-term small-scale field trials and laboratory work.

Suggestions for structure and membership of the overarching body are listed under section 2.

5. *The capacity of Government to be an "intelligent customer" for the advice it receives*

We have welcomed the formation by the Government of the Ministerial Committee on Biotechnology which will have an overseeing role to play in biotechnology policy as a whole. Nevertheless it is important that policy decisions made by this group are informed by a suitably broad basis of knowledge. The overarching body which we have recommended report to the Ministerial Committee, will need to contain consumer and environmental representatives, and experts on ethics and legal issues as appropriate, in addition to adequate scientific expertise. Such a body would provide a suitable breadth of knowledge to monitor wider issues and long term developments.

In addition, we have previously made several recommendations to government regarding its use of Chief Scientific Advisors (CSAs) as a tool to inform policy formation in such complex areas. Departmental CSAs were established as part of reforms in the 1970s, to ensure that Departments could act as intelligent customers for, and users of, the research and advice they commissioned. However in many Departments it has become increasingly difficult for them to raise issues with Ministers at their own initiative. A key role for CSAs is to convey problematic issues to Ministers on which it is necessary to seek scientific advice. To be effective, CSAs must therefor participate in all critical policy groups. They must also maintain extensive networks with the scientific community outside Government departments in order to be alert to current issues and advice. CSAs must also be able to guide Ministers and Permanent Secretaries on the range of policy options available to them in the light of scientific understanding of a given issue.

We recommend increased openness and a fuller involvement of the Chief Scientific Advisor in scientific issues within each Government department. To enable that to happen, the CSA should routinely be involved in meetings of appropriate Cabinet Committees, and should be alerted by the Cabinet Secretary to all science and technology issues being considered at Cabinet level. The CSA should also be copied the papers on science and technology related issues emanating from within departments and from specialist advisory committees.

In addition, we recommend that key issues arising within, as well as across, Government departments should be raised at the Committee of Departmental Chief Scientists chaired by the CSA, although we recognise that a useful start has been made on trans-departmental co-ordination already.

Additional information

The Society would like to draw attention to the following Royal Society publications which are of relevance to this subject: *The Scientific Advisory System (June 1998), Genetically Modified Plants for Food Use (September 1998), Regulations of Biotechnology in the UK* (Feb 1999) and *GMOs and the Environment* (April 1999). Additional copies of this response and the above publications are available from The Science Advice Section at the Royal Society (rebecca.bowden@royalsoc.ac.uk tel: 0171 451 2588 fax: 0171 451 2692). All publications are also available on the Society's web page (www.royalsoc.ac.ul).

23 March 1999

APPENDIX 43

Memorandum submitted by the Royal Commission on Environmental Pollution

1. In October 1998 the Commission published *Setting Environmental Standards.* This called for a new approach to deciding environmental policies, drawing on rigorous and dispassionate analysis, but with greater sensitivity to people's values. The Commission would particularly draw the Select Committee's attention to the discussion and conclusions about scientific assessment contained in chapter 2 of the Report (copy attached)[47]. For convenience, the main conclusions are summarised in this memorandum.

2. In relation to scientific assessment, the overall message of the report was that scientific understanding is, and must remain, the essential basis for environmental standards. Procedures have been developed for assessing the effects of substances on human health and the natural environment, and a wide range of data is used. The data that would be most relevant, however, are often lacking, and the available data are often subject to much uncertainty. In seeking to base decisions on environmental evidence, there needs to be awareness of the nature of such uncertainties, and their implications. This led to more specific conclusions about the role of scientific advice, which the Commission believes may have a wider application. There are of course other crucial components in the decision procedure besides scientific assessment but these are not discussed in this memorandum.

Role of Scientific Assessment

3. It has long been a central theme of UK environmental policies that decisions should be based on what has frequently been called "sound science". Until recently, little attention was devoted to examining what constitutes sound science, either generally or in the context of deciding environmental policies and setting environmental standards.

4. The Commission believes that environmental policies should have a sound scientific basis, and that there is an adequate scientific basis for most such policies at present. There is, however, a widely held view that scientists can provide the answer to whatever environmental issues are under consideration. Science is not a matter of certainties but of hypotheses and experiments. It advances by examining alternative explanations for phenomena, and by abandoning superseded views. Whilst it has provided very powerful tools for gaining understanding of complex environmental processes and systems, in many cases damage has been caused to health or the natural environment because of gaps in understanding. Such incompleteness is inherent in the nature of science, especially environmental science, which deals with the world outside the laboratory. In a scientific assessment of an environmental issue there are bound to be limitations and uncertainties associated with the data at each stage.

5. Within the established procedures of "regulatory science", there are major sources of uncertainty in the conclusions reached both about effects on human health and effects on the natural environment, not to mention the considerable and inevitable uncertainties about the pathways of substances. The conventional approach in countering such uncertainties is to apply safety margins to the scientific data when setting environmental standards. The extent of those safety margins in any given case is essentially a matter of judgement.

6. One reason why environmental policies cannot be decided on the basis of scientific evidence alone is that there needs to be a prior stage, to define what the problem is, frame questions and formulate policy aims.

[47] Not printed.

This will determine the relative emphasis to be placed in a given case on scientific assessment and on other components in the decision procedure, and which types of scientific assessment should be carried out.

7. Decisions over whether to release pollutants into the environment raise questions of values which cannot be answered simply by referring to the scientific evidence. Estimation of the assimilative capacity of the environment is a scientific procedure. Judgements on whether, and to what extent, that assimilative capacity should be used in particular circumstances, or the degree of precaution that should be exercised in taking policy decisions, are part of a wider political process. A clear dividing line should be drawn between analysis of scientific evidence and consideration of ethical and social issues which are outside the scope of a scientific assessment.

Output from scientific assessment

8. To gauge the extent to which there has been a shift over the last 20 years in the kind of output sought from scientific assessment, a comparison can be made between a description of UK practices in setting environmental standards published by the Department of the Environment (DOE) in 1977 and a lecture given (in a personal capacity) by the Chief Scientist of DOE in 1996.[1] The 1977 account said "The first requirement in setting standards or objectives is a realistic appraisal of all relevant scientific data, particularly evidence of damage in relation to dosage"; and also that "The tendency in setting standards in the United Kingdom is less to seek an absolute scientific base than to use scientific principles and all relevant and reliable evidence".[2]

9. In his 1996 lecture, the DOE Chief Scientist spoke of "critical assessment" rather than "realistic appraisal", referred not only to evidence of damage but to evidence for concerns about future damage, and emphasised that the assessment must reflect the state of uncertainty about the evidence and cover all possible interpretations of it. He also emphasised the need to deal with possible sources of bias in the assessment.

10. The following quality control criteria were offered for scientific assessments of environmental issues:

- A sound science assessment reviews all the scientific evidence, not just the most recent research;
- The assessment should display what is held to be beyond dispute, what is the range of speculative interpretations of the data, and weightings as to their likelihood;
- The assessment must be undertaken with peer review if any element is likely to be speculative;
- The assessment must be undertaken by a multi-disciplinary panel with a secretariat if speculative issues relate to discipline sensitive assumptions. (This reduces bias arising from the inherently different approaches of different disciplines);
- The review's emerging findings should be open for public comment at an interim stage. (This may help quality control by uncovering new data which have been collected but not published (researchers, and journals, are generally reluctant to publish negative findings) and by uncovering new interpretations of existing data).

11. The requirement for sound science as the basis for environmental policy is not a requirement for absolute knowledge or certainty and should not be interpreted as such. A conclusion that there is insufficient information available to carry out an assessment which policy-makers have requested may represent sound science.

12. When considering the process of scientific assessment and its output, two issues need to be addressed. First, is the science well done, and are uncertainties and limitations in the data properly recognised? The answer to this question determines whether the assessment represents good science. Second, does the science provide a firm basis for policy decisions? The answer to this question determines how useful the assessment will be to the policy-maker, whether decisions will have to be taken in the face of uncertainty, and whether further studies (perhaps including experimental work) should be carried out.

Presentation of Scientific Assessments

13. To be helpful to policy-makers scientific assessments should indicate clearly what is known or considered to be indisputable, and what is considered to be speculative.

14. Assessments should be transparent. They should contain a succinct narrative summary covering the underlying scientific basis, uncertainties in the evidence and the rationale for any methods used to cope with variability and uncertainties (for example, any safety factors used) and the assumptions implicit in their use. The quality of the assessment and its results and the confidence placed in them will be higher as a result of more open and transparent presentation.

15. In 1997 the Government's Chief Scientific Adviser produced a set of principles (the May principles) to guide Government departments and agencies on the use and presentation of scientific advice in policy making.[3] These principles cover, amongst other issues, the use of a wide range of expert sources, and early peer review of data. They emphasise that "Scientific advance thrives on openness and competition of ideas."

16. In view of the uncertainties in scientific assessments of environmental issues transparency is especially important. An approach to assessing the "pedigree" of scientific data, from both cognitive and social aspects, has been proposed by Funtowicz and Ravetz.[4] Other things being equal, experimental data score highly in

terms of pedigree, but in the environmental field they are unlikely to be available to illuminate the issues that are of most concern. Other kinds of information may be more useful than experimental data that are, at best, of only marginal relevance.

17. Another important consideration in a situation of high uncertainty is the overall impartiality of the procedures used for assessment. Judgements can be swayed, perhaps imperceptibly, by one or another kind of vested interest. One much criticised feature of regulatory science has been the extent to which experts in an industry, the contract laboratories carrying out the standard tests for it and the regulatory body itself have functioned in some instances as a largely closed community.

18. A scientific assessment should present the range of possible interpretations of the available evidence, or the range of scientific possibilities and options concerning a particular course of action, accompanied by acknowledgement of the assumptions and uncertainties implicit in the assessment. The output of a scientific assessment should not normally be presented as a single option or statement; an assessment yielding a single answer (especially a single number) may give a spurious impression of accuracy. The precise way in which the output of an assessment is presented depends on the type of assessment being carried out and the type of environmental concern that is being addressed.

Implications for scientific research

19. Two issues for scientific research arise out of this discussion. The first is that it is necessary to build review processes and the potential for revision into standard-setting procedures, and to ensure that research and monitoring are undertaken to provide inputs to those reviews. Scientific knowledge can move rapidly and standards must be readily adjustable and regularly reviewed, so that new insights can be incorporated.

20. High safety margins resulting from incomplete knowledge and the exercise of precaution may result in financial incentives to further scientific investigation in order to reduce the margin of uncertainty and revise the level of a standard on the basis of evidence rather than precaution.

21. The May principles on science and policy highlight the importance of a more pro-active approach to resolving scientific uncertainties through targeted research, stating that:[5]

> Departments should systematically review priorities to see whether funding needs to be directed to programmes of further research to illuminate outstanding areas of uncertainty identified [during assessment].

22. The second issue for scientific research, also highlighted by the May principles, is the ability of government to respond to new environmental issues. Within their own programmes of research, Government Departments seek to maintain "adequate support for broadly-based longer term research to help them identify and/or respond to new and unexpected findings". OST monitors these procedures. Despite Departments' best efforts to anticipate as early as possible those issues for which scientific advice or research will be needed, some issues will inevitably arise with little or no prior warning. In the Commission's view, Departments should ensure that they have the capacity to recognise the implications and to react quickly and efficiently to such crises.[6] To prevent development of new understanding being restricted by established regulatory procedures, vested interests or small closed communities of experts, publicly funded programmes of environmental research should include provision for independent investigation and inquiry.

References

1. Fisk, D. (1997). Sound science and the environment. *Science and Public Affairs,* Spring 1997, 46–49.

2. DOE (1977). *Environmental Standards. A description of United Kingdom Practice.* The Report of an Inter-Departmental Working Party. Pollution Paper No. 11. HMSO. See paragraphs 13 and 19.

3. Office of Science and Technology (1997). *The Use of Scientific Advice in Policy Making.* DTI. March 1997.

4. Funtowicz, S.O. and Ravetz, J.R. (1990). *Uncertainty and Quality in Science for Policy.* Theory and Decision Library: Series A: Philosophy and Methodology of the Social Sciences. Volume 15. Kluwer Academic Publishers, Dordrecht.

5. Office of Science and Technology (1997), paragraph 10.

6. Office of Science and Technology (1997), paragraphs 3–4.

27 April 1999

APPENDIX 44

Supplementary Memorandum submitted by Monsanto plc, following the evidence session of 10 March

Question 1: Legal action as regards claims of "GMO-free" by operators in the food chain

Question from Dr Williams:

(Refer to transcript of the evidence for the full context)[48].

The request for further clarification regarded the extent to which (if any) Monsanto may have opposed labelling in the United States and that Monsanto may have taken action against companies which labelled products as "GMO-free".

Written Response:

Monsanto has not taken legal action in any country against any individual or group on the basis of labelling of foods as regards the content or otherwise of genetically modified material or its derivatives.

General Background Information:

Further, the basis for "GMO-free" labelling would be acquisition of a supply of GMO-free raw materials. Following the introduction of the Monsanto Roundup Ready® soybeans in the United States, several independent groups did provide lists of suppliers who claimed they could provide a source of "GMO-free". These claims were not contested by Monsanto. It is also our understanding that United States based grain traders also offered to supply "GMO-free" soybeans to those who made enquiries about such supplies. Monsanto did not contest such offerings.

Also as pointed out during the presentation of our verbal evidence, Monsanto is participating in official EU schemes to develop a technical basis to allow "GMO-free" labelling to occur and which will improve the legitimacy of such claims.

As regards legal challenges regarding labelling in the United States, it is only the FDA (Food and Drug Administration) who can take action for a failure to follow its (labelling) rules.

Further, FDA rules state that claims as regards "not produced from" are allowed so long as the claims can be substantiated and the consumer is not being misled. Monsanto has no issue with these provisions.

Although the Committee questions were obviously focused on genetically modified crops, with regard to bovine somatotropin use in the United States, another product derived from biotechnology, Monsanto took action against two dairy interests under domestic "unfair competition" legislation. Those cases involved the alleged use of pejorative symbols or language on the labels, beyond mere labelling for the non use of BST, which created the false impression that those products were safer or purer than dairy products from cows supplemented with BST. However, Monsanto did not contest any use of the allowed terminology "not produced from" which continues to be used.

Question 2: US Decisions as regards the finding substantial equivalence of GM and non-GM crops

Question from Dr Jones:

(Refer to transcript of the evidence for the full context)[49].

The Committee requested further information as regards any role Monsanto may have played in the determination of "substantial equivalence" of genetically modified and non-genetically modified crops and its relation to labelling.

Written Response:

The concept of "substantial equivalence" was originally enshrined in guidance material for regulatory structures and decision-making which was developed by Member States as a result of discussions within the OECD published in 1993. All participating States, including the United Kingdom, the European Community Member States and the United States participated in the development and agreement of this principle.

The principle was developed for the purpose of providing a basis on which to evaluate the safety of crops and food products originating from genetically modified crops.

In the interests of complying with international agreements, the United States subsequently adopted the principle into its own food policies in 1992 (The Food and Drug Administration: Food Labelling; Foods Derived from new Plant Varieties) as did the European Union within its own Novel Foods and Novel Foods

[48] HC 286–iii.
[49] HC 286–iii.

Ingredients Regulation which was adopted in 1997. However, for the purposes of labelling only, the European Union adopted a further additional principle which was the concept of "no longer equivalent".

Therefore, as regards "substantial equivalence" and "labelling", in the United States and as stated in our verbal evidence presented by Dr Waters, the FDA initiated a formal consultation process to determine its policy on labelling of foods originating from genetically modified crops. In the process, the FDA published in the Federal Register, a proposal for labelling which was open to public comment. Monsanto gave its own written comments on the draft policy as did many others. The FDA in its fact finding mission also held discussions with industry groupings in which Monsanto participated, generally through the US Biotechnology Industry Trade Association, BIO.

As noted in responses to the previous question, the FDA policy does allow operators to make such claims as "not produced using genetically modified crops" provided such claims are not misleading to the consumer.

Question 3: Independent data on the reduction in crop chemical use associated with the introduction of genetically modified cotton crops.

Question from Dr Gibson:

(Refer to transcript of the evidence for the full context)[50].

In this case, Monsanto offered to provide further information from independent sources regarding reductions in chemical use following the introduction of genetically modified cotton.

The sales of cotton seed are through seed companies, and only a small proportion of these sales are from companies within the Monsanto Group. While Monsanto has made its own evaluation of the reduction in insecticide use, independently generated data provides a much more uniform evaluation of the effect on insecticide use within the cotton crop.

There is a substantial body of published data and comment from on-farm commercial practice. Of the many reports of the reductions in chemical use the following articles are attached (and which include further references)[51].

Professor R H Smith, National Cotton Council, 1997 Proceedings: Beltwide Cotton Conferences, 6-10 Jan 1997.

Cotton Insecticide Sales Drop, Cotton Grower, 1 March 1997.

Bug Off, Arizona farmers sow hopes that genetically engineered crops will KO bollworms, MESA Tribune, 20 August 1997.

Farmers give Roundup Ready good reviews, Delta Farm Press, 6 December 1997.

Economics of Bollgard versus non-Bollgard Cotton in 1998, Beltwide Cotton Conferences, 1998.

Alternatives to cotton cultivation save soil moisture, avoid root damage, Covington News, 11 August 1998.

Resistance reality, Mid-South Farmer, March 1999.

Management Altered: Insect Changes seen in Alabama Cotton, Southeast Farm Press, 17 March 1999.

In Georgia Cotton: Tobacco bollworm cause of concern, Southeast Farm Press, 17 March 1999.

Cotton growers accepting biotechnology products, Delta Farm Press, 2 April 1999.

Generally speaking, it can be concluded that extremely large reductions in chemical insecticide use against the cotton bollworm pests has occured in the case of insect protected Bt cotton. Calculating from the basis that spraying has been reduced from anything up to 12 sprayings during a growing season to between zero and four, with the majority at the former allows the conservation estimate that reductions have been between 80 and 90 per cent. This is significant when one considers that in the United States cotton as a crop consumes the largest proportion of all crop chemicals.

Question 4: Monsanto UK investment in biotechnology research and development

Question from Mr Jones:

The Committee requested further information as regards Monsanto investment in biotechnology research and development in the UK. (Refer to transcript of the evidence for the full context)[52].

Monsanto has consistently viewed UK research institutions as world leaders in research and development in modern biotechnology and continues, as it has for many years in the past, to support substantial levels of research and development in the UK. UK research and development programmes are considered essential

[50] HC 286–iii.
[51] Not printed.
[52] HC 286–iii.

stepping stones for the long term entry to the UK and European market places. Naturally, levels of investment will vary from year to year and from programme to programme.

Below is a representative list of research and development projects in crop biotechnology the United Kingdom currently under way in 1999.

1. Biodiversity studies at the Institute of Arable Crops Research (IACR).

Current efforts are focused on developing further substantial data packages regarding the ecological/biodiversity impacts of genetically modified herbicide tolerant sugar beet. It is estimated that the cost of this research in 1999 will be some £120,000.

2. BRIGHT Project (Botanical and Rotational Implications for Growing Herbicide Tolerant crops)

This is a joint three year project involving both Government institutions and private industry to study the cultivation of herbicide tolerant oil seed rape and the potential implications for farming practice and other crop and wildlife species. Those involved include MAFF (SAPPIO/LINK project), HGCA, Morley Research, NIAB, Scottish Agricultural College and IACR. The industry partners are Monsato, AgrEvo and Cyanamid. Monsanto contributes substantial human resources as well as funding of £16,000 per annum.

3. Reducing soil erosion and improving soil flora and fauna.

This study is being carried out at the Morley Research Centre and is initially a one year project to investigate the potential environmental and agronomic benefits of combining the RR sugar beet system with eco-tillage (minimum tillage). Eco-tillage is a technique widley used in other geographies and has shown to both reduce soil erosion and increase the levels of beneficial soil flora and fauna thus improving soil productivity. The Monsanto investment in the project in 1999 is estimated at £7,000.

4. SCIMAC Project (studies of the effects of large scale plantings):

The project which has been initiated for a three year period is part of the commitment made to the UK to manage and monitor the commercial introduction of modified crops in a responsible manner and with reporting of crop performance. The project is industry-wide and supported by the seed industry, National Farmers Union and the BAA as well as the "biotechnology companies" such as Monsanto, Advanta, AgrEvo and Novartis. In 1999, it is estimated that the Monsanto contribution to the project will be of the order of £35,000.

5. Study of the molecular interactions of double tolerant (LL & RR) oilseed rape.

This three year DETR project is being carried out at the John Innes Research Centre and is due to terminate in 1999. Monsanto has contributed significant technical expertise and seed material to those administering and carrying out the project.

6. Characterisation of wheat lines with broad spectrum resistance to obligate fungal pathogens.

This project is under the JIC Link scheme through a British Biological Science Research Council (BBSRC) three year post-doctoral fellowship to characterise wheat lines with broad spectrum resistance to obligate fungal pathogens. Monsanto contributions are estimated at some £20,000, mostly as technical and management expertise but also including in-house resident training.

7. Study on the wheat fungal pathogen Take all (Geaumannomyces graminis var tritici).

This research project started in 1998 and is being carried out at the JIC, Norwich is involved with among others, taxonomic investigations of *Gaeumannomyces graminis* (Take all) isolates using molecular biological techniques. Take all is a serious fungal disease of wheat which most often occurs in Northern European climates. The Monsanto investment in the research is of the order of £60,000 per annum.

27 April 1999

APPENDIX 45

Supplementary memorandum submitted by Dr Arpad Pusgtai

BIOLOGICAL TESTING OR LEAVING IT TO CHANCE?

Some of the ideas described here have been prompted by a request from the European Union DGXXIV responsible for Consumer Policy and Consumer Health Protection to start a debate on customer acceptability for genetically modified (GM) food, the regulatory process in the EU and to describe some of the main principles of biological testing which in our view and based on our experience ought to be seriously considered for the future. Clearly, these ideas are also relevant to the remit of the House of Commons Science and Technology Committee's recent inquiry and therefore it was decided they should be included as a supplementary memorandum to the Committee to help their deliberations.

The media frenzy following the TV programme Granada's "World in Action" on 10 August 1998 in which it was claimed that feeding rats on diets containing genetically modified (GM) potatoes resulted in deleterious effects on their metabolism and the immune system was surprising enough but even more astonishing was the almost histerical reaction of some scientists, mainly plant molecular biologists, to this piece of news. Most animal nutritionists were taken aback by the furiousness of the comments which were possibly a knee-jerk reaction of real or imaginary damage to the self-interest of some practitioners of biotechnology coupled with their ignorance of the basic tenets of nutritional science. It is almost certain that had our apparently negative results been obtained at the Rowett Research Institute in Aberdeen during the course of nutritional testing of normal animal feedstuffs and not GM-potatoes, no notice would have been taken by the biotechnology industry. Or even more likely, had our results been favourable to GM-science these would have been hailed as a great scientific advance and our reputation increased. Indeed in our recent work at the Rowett when we obtained "good" results on testing GM-peas (to be published later this year in The Journal of Nutrition) using methodologies similar to those used in our GM-potato studies, these were regarded by biotechnologists as a positive contribution to GM-science. It appears that although most nutritional journals are full of papers of studies carried out with plant-based diets using a similar approach to that in our GM-work, most plant scientists are unaware of these. Indeed our group alone must have published something like 30-40 of such papers in the last 20 years and, regardless of whether the results were good or bad, they were taken on board by the feed industry without accusing us or other authors of trying to stop the progress of science.

As plants have evolved for the propagation of their species and not to be eaten by man and animals, it is not surprising that plants present us with quite a few nutritional problems. Plant proteins are generally less digestible than their animal counterparts, their amino acid composition is different from ours and also plants contain many antinutrient proteins, including lectins, digestive enzyme inhibitors and other factors and low molecular weight harmful to secondary metabolites which need to be dealt with by processing before these plants can be included in human/animal diets. Papers dealing with the identification of antinutrients and establishing methods for the reduction/elimination of their harmful effects on the gut, other vital organs, the endocrine and immune systems and gut bacteria must be counted in the thousands in the nutritional literature. This makes a stark contrast to papers on the nutritional evaluation of GM-food, of which only one full paper exists, published in The Journal of Nutrition by an American group in 1996. Thus, there is a strange paradox that when it comes to animal feedstuffs, even those of soya-based, the nutritional and feed industry accept the need for thorough animal testing and do not rely on compositional analysis alone. As a result animal feedstuffs are generally more thoroughly tested than human food, whether GM or not. Even new cultivars of familiar species which are compositionally similar to varieties already used in food/feedstuffs can have strikingly different biological values as demonstrated by the toxicity of most kidney bean cultivars in contrast to Pinto beans which are not toxic. Therefore new cultivars are usually tested before they are accepted for inclusion in animal feeds. In most instances novel sources of foods are also tested on animals before their introduction into the human diet. The principle of gradualness in accepting such foodstuffs has been operated by mankind over centuries. Indeed, in the paper to be published later this year on GM-peas, we recommended that, although short-term tests with rats appeared to indicate no harmful effects, these GM-peas should first only be introduced into animal rations and at a low level of inclusion. This gives a period of grace to allow the animal industry to monitor any potential development of risks and to evaluate the safety of GM-peas for possible future human use.

A cautious and common-sense approach based on animal testing and gradualness in introducing GM-food has a great deal to recommend. It is also likely to be regarded acceptable and transparent by consumers, particularly if testing is not only done by the biotechnology companies which want to introduce them but also by independent laboratories. Some of the biological testing methodology is already available and novel techniques are being developed all the time by independent research laboratories as part of their scientific remit and/or in conjunction with the feed industry. Thus, the biotechnology companies can easily adopt these methods and/or develop their own to supplement independent biological testing on behalf of the consumer.

Biological testing

1. The whole concept of substantial equivalence needs to be re-thought and put on more rational and scientific foundations. The apparent lack of significant differences in raw compositional data between transformed and non-transformed lines is singularly unhelpful as, depending on growth conditions, composition can vary within wide ranges regardless of whether parent or GM lines are taken. As after the transformation of the parent plant many selection and potential back-crossing steps are usually made, the strict scientific basis of comparing the parent with its GM-lines is no longer there. For meaningful comparisons therefore the parent and transformed lines must be grown under identical and strictly controlled conditions, preferably right from the beginning and treated and harvested the same way. To establish true average compositional values and their range of variability, several of the individual plants of the parent and different GM lines respectively should then be analysed. It would be desirable if, in addition to comparing macro constituents such as proteins, starch, lipids, etc, of the parent and GM-lines, their contents of known biologically active components could also be compared. Unfortunately, possible new components arising out of non-intentional compositional changes would in most instances escape detection. Clearly, a thorough analysis of the GM-material and its comparison to its non-GM counterpart is an essential first step in the testing process before its release. However, even with this stricter compositional comparison, the regulatory authorities' reliance on substantial equivalence as the sole or the main requirement for the release and food use of a GM-crop is no longer acceptable.

2. Reliance in the regulatory process on *in vitro* tests can only be accepted as preliminary, particularly when appropriate *in vitro* tests are available. Thus, the assertion that a GM-product is degraded by acid or pepsin or other proteases in the test tube is not acceptable when the evidence is only based on *in vitro* simulation of stomach/gut degradation experiments because it is common knowledge that many plant proteins/lectins which are degraded *in vitro* are fully stable in the gut *in vitro*. In most instances the survival of GM-material in the gut can easily be demonstrated by preliminary *in vitro* animal tests. Thus, the amounts of GM-products can be estimated by immuno-ELISA analysis or other more conventional chemical techniques in gut washings of rats (or other animals) gavaged with the GM-material. Additionally with GM-lectins including Bt-toxin (*Bacillus thuringiensis* toxin) the presence/absence and/or epithelial binding of the GM-material should also be demonstrated by immunohistology. Similar considerations should apply to the survival or degradation in the digesta of foreign DNA, including the promoter used in the GM-construct. Rather than to accept that all foreign DNA ought to be degraded in the gut, the same or similar metholodogies which are used in the transformed plant to show the presence of the DNA from the construct, should also be used in gut washings or even the epithelial cells to ascertain whether recognisable construct DNA fragments are present or absent.

3. It is not sufficient as done presently that stability, biological activity, immuno and allergenicity and hormonal studies are performed with the recombinant material from *E. coli* rather than with the GM-product isolated from the GM-crop. It is well-known that post-translational modification, including glycosylation, amidation and proteolytic processing, etc is done differently in prokaryotes and eukaryotes. Moreover, these processes are usually different even in different eukaryotes. As all these have an important bearing on the biological behaviour of the GM-product, the gene product must directly be isolated from the GM-crop and characterised and possibly be identified with the product of the same gene in its natural plant.

4. There is now wide agreement that animal tests must be incorporated into the GM regulatory process even though most peoples' views diverge about the precise details of what is to be included in the tests. However, some general principles and methods can be "borrowed" from feedstuff evaluation studies. Thus, it is best to start the feeding trials with young rapidly growing rats or other rodents before progressing to farm animals. Appropriate iso-proteinic and iso-energetic diets will have to be formulated in such a way that most of the dietary protein is preferably derived from the plant material to be tested. The following diets need to be tested as a minimum: GM-diet, parent-line diet and a diet in which the parent line is supplemented with the isolated gene product at the same level as it is expressed in the GM-line. Additionally another diet group is regarded useful in which the parent line is supplemented with the gene product isolated from its original source but again at the same concentration as it is expressed in the GM-line. The animals to be fed these diets are selected into groups of animals of similar weight (at least five animals per group) and the experiment is best carried out with young animals which are individually housed to allow the collection of individual urine and faecal samples for the determinaton of Net Protein Utilisation (NPU), Nitrogen Balance, Feed Utilisation Ratios, etc. First, short-term, usually 10 day, experiments are performed under strictly controlled conditions of pair-feeding. Then depending on the availability of sufficient GM-material, the feeding tests could be appropriately extended. The animals should be blood-sampled before, during and after the completion of the experiments and the sera used for immune studies (lymphocyte proliferation assay, Elispot, etc) and the estimation of hormones (insulin, CCK, etc) and other blood constituents. During the experiment the animals are weighed daily and any abnormalities observed. At the end of the experiments the animals are humanely killed under anaesthesia, preferably two hours after the last feed, fully dissected, the gut rinsed out and the contents saved for possible further studies (analysis of food components, gut enzymes, GM-products, DNA, etc), suitable sections taken for histology, wet organ weights recorded and finally the organs and carcasses freeze-dried and weighed again and subjected to compositional analyses if needed. Results are then subjected to suitable statistical analyses, such as one-way ANOVA, paired comparisons by student's t-test

(or Tukey's test) and most importantly to multivariant analysis to identify possible contributions by the transgene expression and the construct to the significance of any differences.

It is clear that if in these feeding tests any of the above variables show significant differences between the animals fed GM- and parent-line diets, the genetic modification must have had significant effects on the utilisation and nutritional value of the crop. Consequently, as under these conditions the effects of the GM-material in the diet on the metabolism and health of the rats are not substantially equivalent to those of the appropriate parent line, the GM-material cannot be accepted for inclusion in the human diet without further testing. Under most circumstances this GM-material may not be acceptable in animal feedstuffs either. If the negative health effect of the GM-diet is also observed with the parent-line diet spiked with the gene product, this gene is not suitable for genetic transformation of plants destined for human/animal consumption. If on the other hand the negative effects of the GM-food are not observed with the parent line diet containing the gene product isolated from either the GM or the original plant, they are likely to be the result of the use of the particular construct or an unwanted and unforseen effect on the genome of the gene insertion. In this case, the gene itself may be suitable for transfer but either another construct/promoter is (are) needed for the genetic modification with which a more suitable GM-crop plant can be constructed or the insertion effect may be minimised by purposeful selection of the best transformant out of the many obtained on the genetic transformation process. Finally, the most important principle must not be forgotten: animal testing is but a first step and its results, even when there are no indications of the animals being harmed by a particular GM-material in their diet, will have to be eventually confirmed by human volunteer studies.

3 May 1999

APPENDIX 46

Letter to Dr Michael Clark, MP, Chairman of the Committee, from Mr Jeff Rooker, MP, Minister for Food Safety, Ministry of Agriculture, Fisheries and Food, following the Evidence Session of 26 April

At the hearing before your Committee yesterday I agreed to write to you with some information about the concept of substantial equivalence which is used to assist the safety assessment process for novel, including genetically modified (GM), foods.

The safety of GM foods is, wherever possible, assessed in comparison with the foods that they will replace. This concept, known as substantial equivalence, was developed by the World Health Organisation and the Organisation for Economic Co-operation and Development and is used extensively as a tool in the assessment process by expert bodies world-wide. This approach arose from the recognition that foods, unlike specific chemical compounds such as pesticides, pharmaceuticals and industrial chemicals, are not always likely to provide meaningful information if tested on animals. This is because their bulk and effect on appetite, as well as on nutritional balance, means that they can only be added to an animal's normal diet at low multiples of the amount that might be present in the human diet. Thus it would be very difficult to pick up any potentially adverse effects, or to relate any effects seen, to an individual characteristic of the food in the majority of cases.

The FAO and WHO held a consultation in 1990 to address this problem. This recommended that safety assessment strategies for novel foods should be based on a consideration of the molecular, biological and chemical characteristics of the food to be assessed and that this should determine the need for, and applicability of, traditional toxicological testing. As a way round the difficulty of tesing foods by traditional methods, the WHO put forward the comparative principle whereby the food being assessed is compared with the traditional counterpart that it is likely to replace. This gave rise to the principle of "substantial equivalence" which was identified as being:

> "A demonstration that the characteristics assessed for the genetically modified organism, or the specific food product derived therefrom, are equivalent to the same characteristics of the conventional comparator. The levels and variation for the characteristics in the genetically modified organism must be within the natural range of variation of those characteristics considered in the comparator and be based on an appropriate analysis of data".

It is important to recognise that "substantial equivalence" is merely a tool to aid the process of safety assessment and to help to identify particular factors that need to be looked at in detail in individual cases. The fact that a GM food may be classed as substantially equivalent to a conventional one does not mean that it is automatically considered as "safe". This process is not an end in itself or a "fast track" for clearance of individual foods and does not obviate the need for a thorough safety assessment to be carried out before a food is allowed onto the market, it merely helps to ensure that any assessment focuses particularly on the more important elements.

When a GM food is compared to its conventional counterpart, consideration is given to both the intentional effects of the modification and also to any possible unintended secondary effects. This comparison involves the use of a wide range of information including agronomic data derived over a number of generations (such as crop-yield, flower impact and common disease resistance in climate tolerance) and detailed compositional requirements on nutrients (proteins, fats, carbohydrates, vitamins and minerals) as well as possible toxicants in both the plant and any derived food product. If all these considerations do not arise any concerns then application of the process of substantial equivalence enables the conclusion to be

drawn that the food is as safe as its conventional counterpart. This must be the ultimate test for a novel food as we cannot say that even those foods that have been eaten for hundreds of years are "absolutely safe".

I hope this rather lengthy explanation helps to clarify this somewhat complex issue but if you require any further information, I shall be happy to provide it.

27 April 1999

APPENDIX 47

Letter to the Committee from Ms Jane Sell, Public Affairs Manager, J Sainsbury plc, following the Evidence Session of 21 April

Further to my letter of 29 April, here follows the additional supplementary information requested by the Committee during the course of the oral evidence session.

1. Q 673–8: Provision of hazard analysis sheets

1.1 Sainsbury's has an established Product Management System which requires all suppliers to have comprehensive audit trails for all own-brand products. For fruit and vegetables, it is the responsibility of the supplier to retain full details of the names, quantities and time of application of any pesticides or other chemicals used during production. The level of detail required is such that it must correlate with specific codes. However, Sainsbury's retains information about the generic name of the pesticides and other chemicals used.

1.2 All pesticides and chemicals must be approved by Government before use. Sainsbury's ensures a list of such products is available to growers so that they may then choose which is the most suitable for their purposes. Sainsbury's does not dictate which pesticides or chemicals should be used.

1.3 Potentially an individual fruit or vegetable could be supplied by any number of different growers (we source from over 6,000 growers via our Partnership in Produce scheme alone) who may have chosen different chemicals from within the approved list and who may each change the use of one pesticide or other chemical to another during a season to reflect changes in climate and growing conditions. Were each fruit or vegetable to have a hazard analysis sheet they would require several during the course of a season which would constantly need updating.

1.4 We base the provision of information to our customers on market research. Last year we undertook research which indicated that generally Sainsbury's customers do not want information which is scientifically complex and alarmist. They stated a preference instead for clearly communicated policies on the basis of which they can trust in our brand and be assured that the traceability and scientific work is well in place. Given that safety data sheets are extremely complex and not consumer friendly, they do not meet with these criteria and we have no plans to introduce them.

1.5 Copies of the three leaflets we currently make available to our customers interested in pesticides and other chemicals used during growing are attached; these are: (i) Integrated Crop Management System brochure, (ii) Integrated Crop Management System: Policy and (iii) Biodiversity on the Farm brochure.[53]

1.6 As pointed out during the oral evidence session, Sainsbury's offers customers a range of organic alternatives to conventionally produced fruit and vegetables.

2. Q 679: Proactive consideration of an ethical issue

Examples of Sainsbury's acting proactively on issues are as follows:

2.1 *Environment Report*

Sainsbury's published its first Environment Report in 1996. We were the first, and remain the only, food retailer in the UK to do so. The purpose of the Report was to set out publicly our environmental objectives and policies, the targets we have set ourselves and our progress in meeting these targets. A copy of our latest Environment Report published in 1998 is attached for information.[54]

2.3 *Sewage Sludge*

The ban on the disposal of sewage sludge to sea which recently came into force under the Urban Waste Water directive was likely to lead to an increase in the disposal of untreated waste to agricultural land for the production of food. Sainsbury's, with other food retailers, has worked with water companies to develop a

[53] Not printed.
[54] Not printed.

framework to ensure waste would be both treated effectively and applied under strict controls to ensure safety is not compromised. This was done without legislation and to prevent any future concerns arising from inadequately controlled practices.

2.3 *On-pack labelling*

Sainsbury's provide on-pack food safety handling advice on a number of products to allow our customers to help them to make informed choices about the foods they eat eg raw milk soft cheese, raw meat and poultry. Such advice is not statutory and is done completely voluntarily, often beyond that of other retailers.

2.4 *Sound fishing*

Sainsbury's was the first UK retailer to support the development of the Marine Stewardship Council, an independent non-governmental organisation working to promote sustainable fishing practices. Our Sourcing from the Wild policy (brochure attached[55]) has clarified Sainsbury's policy on selling shark meat, for example. Two species sold at Sainsbury's were checked and one is no longer sold as it was defined as a vulnerable species according to the World Conservation Union Red List.

3. Q680: Membership of Sainsbury's Biotechnology Advisory Committee

3.1 The external and internal members of Sainsbury's Biotechnology Advisory Committee were as follows:

External:

- Professor David Ingram, Regius Keeper, Royal Botanic Gardens, Edinburgh, *Botanist.*
- Professor Chris Leaver, Dept of Plant Sciences, University of Oxford, *Biotechnologist.*
- Dr Roger Straughan, Dept of Arts and Humanities in Education, University of Reading, *ethicist.*
- Barbara Saunders, Freelance consultant to consumer groups, *Consumer representative.*
- David Richardson, *Farmer, Chairman of LEAF (Linking Environment Agriculture and Food), freelance agricultural journalist.*
- Dr Julie Hill, Director of Biotechnology Programme, The Green Alliance, *Environmentalist.*

Internal:

- Dr Geoff Spriegel, Divisional Director, Technical Division.
- David Thurston, Head of Group Legal Services.
- Alison Austin, Senior Manager, Environmental Management.
- Geoff Brown, Senior Manager for Retail Food Safety and Technical Services.
- Jane Sell, Public Affairs Manager.

4. Q693: Independence of Food Standards Agency

4.1 Sainsbury's supports the definition of independence of the Food Standards Agency set out in the Government's Green and White Papers and in the Draft Bill. In summary, we support the creation of an agency which will be seen to be independent of particular industry interests, as well as being independent of Government but responsible to Parliament through the Secretary of State for Health.

5. Q703: Establishment of thresholds for non-GM

5.1 In the absence of any statutory threshold levels for adventitious contamination of identity preserved non-GM soya beans, Sainsbury's initially used for guidance, the industry accepted level for adventitious contamination in hard wheat used in the production of durum wheat pasta, ie 3 per cent.

5.2 We understand that the EU Commission is currently considering draft legislation which includes a threshold level of up to 2 per cent and that the debate about the point in the supply chain to which this should apply is continuing, ie to soya beans at the farm gate or ingredient delivered to the food manufacturer.

5.3 Sainsbury's has no strong view about the actual level but, for practical reasons, believes that any threshold set should be easily verified by analysis. Current GM analytical methods are only semi-quantitative with results being reported as low as 0.1 per cent depending on the technique and the laboratory used.

5.4 If the level of adventitious contamination is to be reduced below customary agricultural industry levels then changes in agricultural, storage, transporation and manufacturing practices will be necessary.

5.5 In terms of verifying our policy of eliminating GM material from our own brand products, Sainsbury's carries out risk assessments on manufacturers' sources of supply and undertakes additional testing at contract laboratories using the latest technology available. We have been at the forefront of a retail initiative requiring laboratories, used by ourselves and our suppliers, to have their analytical tests accredited to a national

[55] Not printed.

scheme, such as UKAS, or alternatively to a commercial scheme, such as the Campden Laboratory Assessment Scheme (CLAS) or Law Laboratories (LAWCRED).

I hope the Committee finds this additional information helpful. Please let me know if you require any further information.

6 May 1999

APPENDIX 48

Memorandum submitted by Soil Association

BACKGROUND INFORMATION

The Soil Association was formed in 1946 to promote a better understanding of the relationship between agricultural practice, human health and the environment. For more than 50 years the Soil Association has been campaigning for more sustainable agriculture in the United Kingdom and for the last 25 we have been involved in developing organic standards which now underpin the rapidly growing market for organic foods.

Initially, the Association was agnostic about genetic engineering. Our position was that we should look at it on a case by case basis. After further research our Council concluded that the technology was incompatible with organic farming and we took action to exclude the use of genetically modified organisms (GMOs) and their derivatives from our organic standards. In 1997 the Council came to the conclusion that genetic engineering had no place in food and agriculture.

OVERVIEW

The Soil Association considers that there have been major failings in both the structure, representation and terms of reference in relation to the establishment of the regulatory framework for the production of GM foods and the release of GM pollen into the environment.

SUMMARY

GM crops trials

The terms of reference and aims and objectives of policy making committees have proved to be inadequate.

The widespread commercial planting of GM crops will lead to cross-pollination of non-GM crops, removing the right of consumers to eat non GM food. This issue has not been properly taken into account by advisory committees.

The precautionary principle has been ignored in favour of an evidence-based scientific approach, resulting in unnecessary risks being taken with the environment and food safety.

No proper assessment has been undertaken of the impact on biodiversity.

No science-based information has either been requested from, or been responded to, from groups representing the interests of neighbouring farmers, organic or otherwise as to impact of GM crops (*"The Dispersal of Maize Pollen"* submitted by the Soil Association to ACRE, 3/3/99—still no response).

Safety procedures for licensing of GM foods

The scientific advice to the Government has come from a small body of experts on the advisory committees who are inclined to approve applications

There has been a failure to apply the same safety procedures for agricultural crops as for medicine.

There has been an inadequate assessment of safety/benefits of GM food.

There has been no-long term testing on animals or humans; as a result available scientific evidence is inadequate for a full evaluation of the risks. In addition there has been insufficient consultation with a broader range of experts such as toxicologists

The scientific advisory system fails to ensure that evidence is challenged and independently verified (especially evidence submitted by biotechnology companies themselves) and does not include active participation by all interested parties.

The regulatory system has failed to cope with rapid scientific developments because advisory committees are too narrowly based both in terms of remit and membership.

Public participation in the GM debate

Almost zero public participation has occurred, although a new and untested technology was being introduced into the food chain and the environment.

Active public participation in the decision-making process is more important than the establishment of an overarching body.

Public participation would enable Government to make decisions based on broader considerations than just science.

The importing of GM foods

The decisions made about GM food and crops should consider questions of ethics, need and the right of the consumer to choose as well as science.

No proper consultation with consumer groups or other interested parties has occurred.

Segregation of GM and non-GM imported products is not maintained by the UK authorities.

Labelling of GM foods

Labelling legislation is inadequate. Industry concerns, ie cost of labelling holds more influence over government decisions than "the right of the consumer to choose".

Segregation of GM and non-GM products is not maintained by the UK authorities. With no records it is impossible to label or to audit and assess the impact of genetically modified ingredients on human/animal health via unmarked GM ingredients.

1. THE ADEQUACY AND QUALITY OF THE SCIENTIFIC ADVICE

At very least the scientific advice to government must be seen to be impartial and independent. This is not the case when it comes to the Advisory Committee on Releases to the Environment (ACRE) or the Advisory Committee on Novel Foods and Processes (ACNFP). Both committees often rely on the biotech industry's own data and risk assessments when advising ministers. Much of this data has not been independently reviewed.

The Advisory Committee on Releases to the Environment (ACRE)

ACRE give the impression of being biased in favour of the biotech industry. For example, it was ACRE who instigated the "fast track" system for applications to release certain GM crops into the environment to be introduced. This procedure effectively removed the public's right to participate in the decision-making process and introduced a "rubber stamp" approach to the evaluation of many applications. So far, ACRE have not turned down a single application to release a GM crop into the environment. ACRE have therefore never seriously addressed concerns about the risk of cross-pollination of non-GM crops by GM crops.

The ACRE has been asked on several occasions to review their previous advice to the Minister following publication of scientific evidence relating to the potential for harm caused by GM organisms. For instance in the case of Novartis's Bt Maize, new research published in 1998 showed that lacewing larvae could be harmed by the Bt toxin when feeding on prey. ACREs responded by saying that although the research was well designed it gave insufficient reason to change their previous advice that the maize should be approved. In 1998 ACRE were also asked to review the risk of cross pollination of an organic farmer's sweet corn with GM maize in Devon, and in 1999 ACRE reviewed Plant Genetics Systems' marketing application for sping oilseed rape in light of new evidence on cross pollination with neighbouring crops and wild relatives. In each case ACRE chose to advise the Minister that the new evidence did not give them cause to change their original opinion—decisions that suggest that ACRE is more interest in defending its initial view rather than advising the Minister on the degree of scientific uncertainty that exists.

ACRE also lacks expertise in several important areas. The committee has no expertise in long distance pollen movement, no farming representative (conventional or organic), no soil scientist, no ethical advisor and no consumer representative. Eight out of 13 of the current members also have clear links with the biotechnology industry.

Ministers should be able to call on other experts when the need arises. For example in the case of the organic farmer Guy Watson, which related to pollen flow from GM crops, advice was given by ACRE despite the fact that none of the committee members have any expertise in this area. When there is concern expressed from outside ACRE, the Minister should consult more widely and treat advice from experts outside ACRE with equal weight to that from the committee.

The Advisory Committee on Novel Foods and Processes (ACNFP)

The ACNFP bases its advice on very limited data supplied by the industry. Its decisions to pass novel foods as "safe" are often based on short term "wholesomeness" trials on animals such as rats, cat fish, chickens and cows. No toxicological studies on the whole GM food are supplied, no human feeding trials, no research into other physiological or biochemical effects are submitted, such as effects on the immune system or endocrine system, and no data is supplied from trials when soya has been treated with glyphosate. In many cases, the ACNFP appears to accept poor quality evidence. In the case of composition analyses, comparisons between varieties of different genetic background are accepted, as well as comparisons between varieties grown in different countries or different years. This means that any differences are almost certain to be masked by these other factors—such procedures would not be acceptable for any published research article, but have been permitted when assessing the safety of GM foods for consumption by the general population.

ACNFP should not be the sole source of advice for ministers on food safety. The voices of the consumer and ethnic communities and processors of non GM food should also be heard.

The use of the concept of "substantial equivalence" as a basis for the assessment of food safety is also of great concern. We agree with the evidence given by Professor James and Dr Chesson, of the Rowett Research Institute, before the committee on 8 March that the use of substantial equivalence is not adequate for the purpose of assessing the safety of GM foods.

It is essential that both the ACNFP and ACRE are reformed as soon as possible by revising their remits and membership. Members of advisory committees should be asking challenging questions of industry and refusing to approve applications unless adequate answers, backed by independent research, have been provided.

2. THE ROLE AND FRAMEWORK OF THE ADVISORY COMMITTEES

There are a number of obvious gaps in the current system. The ethics of a particular modification or release are not adequately covered by the advisory system.

There is no system for assessing the economic and social consequences, such as impacts on farmers and the rural community. There is also no opportunity under any of the regulations relating to genetically modified organisms or micro-organisms for the public to have any input which will influence the approval process. It should also be noted that liability for harm caused to human health, the environment or economic damage is not considered.

The risk assessments for releases into the environment or health impacts have a number of short-comings.

- Risk/benefits analysis is poor and often only examines a narrow range of options. For example, herbicide resistant crops have only been compared with conventional intensive crops—ignoring the range of other agronomic options available in different farming systems, from the use of weed thresholds for herbicide reduction to organic practices.
- The long-term health effects are not considered, or tested for. Therefore the data can't be seen as sufficient evidence to carry out real analysis of risks. The precautionary approach is needed.
- The long-term effects of releases are not adequately assessed nor supported by relevant research. For instance, issues relating to cross pollination and the resulting impacts on wild relatives of crop plants are frequently poorly researched or supported by relevant literature. Indirect effects, such as the impact on biodiversity of the prolonged use, season after season, of broad spectrum herbicides are ignored.
- There is a lack of baseline knowledge about the environment into which the GMO is being introduced, in particular the ecology of agricultural systems and of soil living organisms. Adverse effects cannot be detected if there is an incomplete understanding of the ecosystem into which the GMO is being introduced.
- Lack of completed research concerning potential health impacts of releases, for example horizontal movement of genes from GMOs to gut micro-organisms. This means that risk assessments are made based upon insufficient information, and must be frequently based upon theoretical assumptions instead.
- The indirect effect of releases into the environment are not adequately assessed because no single body has responsibility for assessing the impact of full-scale commercial use of a genetically modified organism (GMO) and associated chemicals.
- Research into the risks and impacts on neighbouring farms and the local environment associated with the release of GMOs is being conducted after they are released rather than before.

The Soil Association is also concerned about another issue relating to the commercial development of GM crops—the secrecy involving approval of pesticides for use on them. The Pesticide Safety Directorate (PSD) and the Advisory Committee on Pesticides (ACP) make decisions without any reference to members of the public and the wider scientific community. The approval of pesticides has been shown to be flawed, for instance a monograph by the Austrian Ministry of Agriculture on the pesticide lindane has just revealed that there are very significant gaps in the data relating to a host of potential environmental, and health effects (the

Monograph was produced by the Austrian Federal Ministry of Agriculture for the EU to assess the inclusion of lindane in Annex 1 of the EC Directive 91/414/EEC). Lindane was approved for a further five years in the UK in 1996. Whether these gaps in data were recognised and ignored by PSD and ACP is not clear because their deliberations were not made public.

There are already applications for registration of herbicides designed to be used with GM crops. There is no opportunity for any organisation or other scientists to make representations on these applications. There is no opportunity for public comment or participation until after the decision has been made, at which point there is no opportunity for appeal. This is completely unsatisfactory.

3. The ability of the current system to respond to rapid scientific developments

The Environment Minister has the power under Article 16 of the 90/220 Directive to revoke marketing consent for any GM crop or products if new scientific evidence emerges. So far there has been a reluctance to use this power in the UK despite assurances from Ministers that they will use the precautionary principle when assessing the safety of GM food and crops. Part of the reason for Ministers' reluctance is the inability of the advisory committees to revise their previous advice. The inertia of the advisory committees has acted as a serious block on effective responses to new developments.

4 Do we need an overarching body to advise and oversee on genetically modified food issues?

If gaps in the present advisory system are adequately filled by giving ACRE and ACNFP revised remits and a more balanced and idependent membership, the need for an overarching body is reduced. It is however essential cost/benefit analyses are carried out and that ethics and consumer choice are brought more strongly into the regulatory process in respect of releases to the environment, food safety, pesticide approval and seed approval.

At present, the Government does not have sufficient information to make a balanced decision. One of the clearest gaps is the lack of meaningful input from the public on the need for and ethics of the use of GM food. There is nothing more personal than what you eat and therefore public involvement in this key area of decision making is vital. Independent scientific advice proves that widespread commercial planting of GE crops will lead to cross-pollination of non-GE crops. This will remove the right of consumers to eat non GE food (a right the vast majority of the public want to keep), but the issue has not been adequately addressed by the advisory committees.

It is Soil Association's view that the priority should be to make the present system more democratic and make use of public opinion and independent advice on the impacts of this technology as part of the application assessment process. The advisory committees must look at the impacts on the right of farmers to grow and consumers to eat GM-free food before releasing GMOs into the environment. There is also of course a risk that any overarching body could be dominated by industry in the way ACRE and ACNFP have done and so fail to command public respect.

In the end it is Government which has to make the decisions as to what is or is not safe to eat or release into the environment and whether they can justify removing the right of consumers to eat GM-free food and removing the right of farmers to grow it. What is at issue at present is not just where their advice comes from but the breadth and quality of the information they receive.

5. The capacity of the government to be an "intelligent customer" for advice

Although genetic modification is a very complex issue, food is a basic and fundamental part of everyone's lives. Decisions about the future composition of our food cannot be based on the advice of scientists alone or on the narrow perspective of how the economy should develop. There are crucial human health, environmental, ethical, social and economic issues which also have to be considered.

Under the present regulatory system we are reliant on industry to tell us what is and is not safe. Scientific advice (often perceived as being dictated by those who write the cheques) is now taken with a pinch of salt by many people following assertions about food safety in the past which proved to be untrue.

When scientists cannot agree even about the basic assumptions on which biotechnology is built, the precautionary principle is the only one to follow. Many of the decisions to be taken are political, as they affect how society, the rural economy and the environment will develop. This technology has the potential to affect every person in the UK. It is therefore right that the population at large is listened to, as well as scientific opinion. Wide consultation on the future direction for food and farming is not only desirable but necessary, in order to protect for future generations the health of the public as well as the environment.

6 May 1999

APPENDIX 49

Letter to the Committee Specialist from the Parliamentary Clerk, DETR, following the Evidence Session of 26 April

We spoke on Thursday and you asked for some additional information following Michael Meacher's appearance before the Committee on 26 April.

Michael Meacher will be writing to the Committee Chairman shortly about English Nature's list of proposed research and ACRE's secretarial staff resources.

So far as Directive 90/220 is concerned, the Directive provides two mechanisms by which individual Member States may prohibit the marketing of a GM product on its territory. Conditions may be attached to a consent to restrict where in the community it may be used. Second, Article 16 of the directive is a "safeguard" clause intended to deal with cases where new information concerning environmental or human safety becomes available after a product has been given clearance. Under these circumstances, the sale of the GM product can be provisionally restricted by a Member State but within three months a binding decision must be taken at Community level on the validity or otherwise of this unilateral action.

Finally, UNEP stands for United Nations Environment Programme.

I hope this is helpful.

10 May 1999

APPENDIX 50

Supplementary Memorandum submitted by Somerfield Stores Ltd

SOMERFIELD POLICY—GENETICALLY MODIFIED FOODS

In future Somerfield will follow a policy of avoiding genetically modified foods and ingredients in all own label products.

To achieve this we will develop products that avoid the use of crops, foods and ingredients that contain genetic modifications but where this is not possible we will minimize their use to particular levels. These are as follows:

In the case of soya and maize purchased as identity preserved crops (ie we know the origin of the crop and believe it to have been grown with seed that has not been subject to genetic modification) then the proposed legally permitted allowance of up to 2 per cent tolerance will be accepted. This may vary in future subject to EU Regulations. Such materials are to be purchased with appropriate levels of "due diligence".

In the case of ingredients, additives and processing aids we will not declare genetic modification where the ingredient, additive or processing aid is present in the final product at less than 0.01 per cent on a weight by weight basis.

We intend to complete our current review of own label products and amend and introduce new artwork by the end of June/early July.

Branded Goods

Branded owners to comply with EU/UK labelling regulations.

13th April 1999

APPENDIX 51

Letter to the Committee Specialist from Mr Nigel Hawkes, Science Editor, The Times

Your letter about GMOs and the Scientific Advisory System has been passed to me. It is the first I have heard of any request from the committee for a memorandum—I am sorry for any unintended discourtesy to the committee and hope that I can briefly provide you with the information you seek.

In general, GMOs are treated no differently from any other issue of public importance. I have been writing about them for at least five years, over most of which period the public showed relatively little interest. As Science Editor, I would together with the Environment Correspondent be the first "gatekeeper" to determine what stories the paper might cover. That is to say, if either of use deemed a story newsworthy, we would offer it to the Newsdesk and if they too found it interesting, would write it. Then it would have to take its chance with the rest of the day's news and either get into the paper, or not.

As for deciding what line to take, that is the responsibility of the Editor and colleagues, who in this instance would include me. The line we have taken in a number of leaders has been in general supportive of GMOs, largely because none of us can see any special reason to be unduly alarmed about them. It is my view that

many of the concerns have been exaggerated, and I have written so in the paper. I cannot speak for my colleagues, but I think that view is generally shared, to a greater or lesser degree, by all of them.

The commissioning of articles is a task which is widely delegated. Articles for the opinion pages are commissioned by one editor, for the science pages by another, for the magazine and weekend sections by yet others. The Editor, of course, has overall responsibility but cannot be privy to every such decision—nor would he want to be. This means that it is impossible to impose any line which would be followed by all commissioning editors. Sometimes sections of the paper might run articles on the subject with which I personally disagree, and over which I would not be consulted, or necessarily expect to be. It would be unhealthy if it were otherwise. So the answer is that the choice of people from whom to commission articles is in the hands of journalists to whom the Editor has delegated that task. They may have widely differing views on GMOs.

Finally you ask what events represent important news. Frankly, this is like asking how long a piece of string is. A story that may be obscure one day can be front-page news the next, usually because it has acquired political rather than simply scientific significance. I wrote a number of stories, for example, about the possible environmental effects of GMOs which either appeared briefly, or not at all, before the subject became politically-charged. Subsequently such stories have been given greater prominence. So you cannot divorce content from context in evaluating what is or is not a majority story. Whole books have been written on "news-value" and what determines it, and I have nothing original to add.

For the record—and I should emphasise that this is my personal view—I consider that Britain's scientific advisory system for GMOs, including the Committee on Novel Foods and Processes, and the Committee on Releases to the Environment, has done an excellent job. All the issues that now so excite the public have been considered by these committees in a dispassionate and rational way. I deplore the suggestion that because their members actually know something about the subject, their advice is suspect. If all government advice is to be regarded in this light, we shall soon have nobody competent willing to serve on advisory committees.

I hope these views are of some assistance to the committee.

7 May 1999

APPENDIX 52

Letter to the Committee Specialist from Mr Charles Moore, Editor, The Daily Telegraph

You informed us yesterday that written evidence was required from The Daily Telegraph by the morning of Wednesday 12 May if it was to influence the deliberations of the Science and Technology Committee. And you stressed that you were interested in the role of the media in the Pusztai affair.

The Telegraph has had fewer than 24 hours to respond to your appeal because your letter of 4 May was not addressed to a named individual, indeed not even to the relevant post (editor, science editor, agricultural editor or whatever—see enclosed letter). We have no record of your letter of 8 March.

As a result, the Telegraph has not had much opportunity to provide you with a considered response. We would, however, like to make a few points.

You asked who decides what line to take. In the case of editorials, I make that decision on the basis of consultations with staff. Two sessions on GM food/crops were held with relevant specialists: Agriculture Editor, David Brown; Environment Editor, Charles Clover; Science Editor, Dr Roger Highfield; Science Correspondent, Aisling Irwin; lobby staff; and leader writers. The Telegraph could also draw on the expertise of its science columnists, Dr Matt Ridley (biologist, respected author and former science editor of the Economist) and Prof Steve Jones of University College London.

In the case of news stories, morning and afternoon conferences are held under the aegis of the editor to help decide news priorities. However, circumstances do not always allow much time for this kind of discussion: the spate of stories began after a decision to follow up a story in the first edition of the Guardian (a story also carried on Newsnight and the Press Association) was taken on the evening of Thursday 11 February, allowing little time for research, confirmation and analysis if it was to meet deadlines for the next day's paper.

It was followed in the first instance by Polly Newton from our political staff after the first edition, and added to a story already written by David Brown and Charles Clover about a dispute between Baroness Young and Jack Cunningham over the substance of English Nature's call for a moratorium on certain GM crops. The night staff was not helped by the fact that the Science Editor, Dr Highfield, who had written up the Pusztai affair the previous summer, was on holiday.

As an example of how a specialist correspondent approaches this kind of story, David Brown, the Agriculture Editor, commented:

"For my own part, I select news on the basis that the information on the GM issue is in fact new or is a new development of what has already entered the public domain.

I regard the question of GM food as probably the most important development in the food and farming industry this century. It is no exaggeration to say that it could very well be the Second Agricultural Revolution

which could provide farmers and consumers with enormous benefits in terms of healthier food produced with the aid of fewer pesticides.

The technology also has the potential to provide society with a wide range of sustainable and renewable "industrial crops" for fuel and raw ingredients for pharmaceuticals. This has important social and economic implications for rural areas in Western countries where food crops are in surplus.

It promises to widen the horizons of food and industrial crop production by making plants tolerant to extremes of heat and cold and resistant to pests and diseases.

On the face of it, genetically modified crops may well "feed the world" and provide much of its fuel and medicines in future.

The downside is that GM crops COULD cause serious environmental damage by unwittingly leading to herbicide-resistant super-weeds. They could also lead to the extinction of many existing plant varieties if farmers throughout the world feel the new "super crops" do a better job.

Something similar happened in Britain to many of our traditional breeds of livestock during the intensification of agriculture in pursuit of higher production. Fortunately, largely due to the efforts of the voluntary Rare Breeds Survival Trust over the past 25 years, this particular rot has been stopped and old bloodlines have been conserved.

In trying to assess the benefits and the risks, and balancing them against each other, I talk to mainstream scientists in the State and private sectors, to farming leaders, consumer groups and environmentalists. I also talk to the main agricultural trade bodies. I also talk with ministers and senior civil servants.

I monitor the Government's own regulatory bodies who licence pesticides, herbicides and keep and referee novel foods and processes. These organisations contain highly qualified experts in their fields—although I bear in mind that they are all human and, as such, are capable of making mistakes. It is part of our job to spot any errors if and when they occur.

The task, out of all this, is to assess what is a real issue, a valid concern, and what is a groundless scary story. It is also to identify genuine, beneficial advances in the technology and what is not.

That is why we check as many knowledgable and trustworthy sources as we can before using our own specialist knowledge of the field to make a factual, balanced judgement on the information we have gathered."

Chronology

Responsibility for the Pusztai story was distributed among general reporters, agriculture, environment and science correspondents.

The science correspondent, Aisling Irwin, attended the press conference on Friday 12 February and the science editor became involved the following Monday.

During the initial period, several concerns emerged. The new research had not been subject to peer review, nor had it been replicated. There were also alternative explanations for the observed effects (the plants' biochemistry may have changed so they produced high levels of other toxic substances, such as alkaloids found in green potatoes).

The underlying aim of the experiment—to put a known toxin into potatoes—seemed an unlikely aim of GM food companies. Indeed, a write up of a Royal Society report in the Telegraph on 9 September 1998 quoted Sir Aaron Klug as saying that to introduce the lectin gene into potatoes was a "scandal". Given the muddle made by Dr Pusztai, an elderly scientist, the previous summer, it seemed prudent to be cautious. Extraordinary claims require extraordinary evidence.

When correspondents attended the Friday 12 February press conference, they were uneasy about the organisers, who seemed reluctant to identify themselves (one can imagine the reaction if it had been discovered that Monsanto had helped to organise an apparently impartial pro GM conference).

It emerged that a shadowy environmental coalition organised the Friday press conference. On Sunday 13 February, the science correspondent with Ben Fenton, a senior general reporter, discussed how there is no-one to trust over this issue. The 20 international scientists who backed Dr Pusztai turned out to be mostly obscure figures. And the lack of peer review was also mentioned.

On the Monday, the Telegraph conducted a poll of 20 scientists to gain a feel for the technical issues that were of most concern (this was done by sending an email to 50 eminent scientists in relevant disciplines who just happened to be on the address book of the office PC. As ever, the expertise we drew on depends on a mixture of factors—availability, discipline, whether they are known to us, and so on).

This scientific straw poll identified that the effects of GM crops on the environment was higher on the scientific agenda than their effect on health. It was tricky to generalise about GM foods, given detailed differences between them. (As with all foods, there are many theoretical risks. These range, in some people, from lowering antibiotic resistance to triggering allergies, and even poisoning. All depend on the gene that is introduced.) The risks posed by GM food to human health were considered theoretical, rather than real, and the majority of scientists said they were happy to eat GM food.

The next day, the political side of the story gathered momentum. We held, on the Tuesday and Wednesday of that week, wide-ranging editorial conferences involving science and environment editors, the Editor, leader writers and columnists to establish the paper's view.

Part of the reason for the meeting was to end the period of being reactive to news about this story and to coordinate policy throughout the paper. During this meeting the view strengthened that, while the Pusztai incident may be red herring, other more important issues relating to dangers of GM crops had not been aired.

On Tuesday 17 February the Telegraph published a draft of a report obtained via Friends of the Earth on the effect of GM crops on the countryside, written in May last year but as yet unpublished. This we reported on our front page had been "stifled" as there was no evidence that the Government had plans to publish the final report, and Michael Meacher had told our Environment Editor that it would be completed "within a couple of months" as long ago as 15 June last year.

Prof Beringer, chairman of ACRE, unfairly criticised the Telegraph in an interview in *Nature* for saying this report had been suppressed. There is no doubt that the publication of extracts in the Telegraph led to its publication and no plans had been made for its publication before that. He also erroneously described the report as an ACRE report, though the report was compiled by the Secretariat to ACRE which comprises civil servants from the DETR. It was therefore a government report, the publication of which is subject to political pressures.

To illustrate how the Government was more concerned by these environmental issues the same day, on 17 February, the paper carried an interview with Sir Robert May, the Chief Scientist, who said that GM crops would "accelerate existing trends toward realising the millennial-old dream of growing crops that no one eats but us. It's the aim of agriculture. And the more successful we get at that, the worse the news for the wild flowers, the insects, the birds and the countryside."

There were many other stories linked with the affair. However, we would also point out the bullish defence of GM crops and food, contained in an interview with Dr James Watson (who helped to launch the DNA revolution). He told the science editor that "the only person harmed so far by DNA is President Clinton."

The page also carried a critique of Dr Pusztai's work by Prof Peter Lachmann, President of the Academy of Medical Sciences, a cosignatory of a letter written to the paper that pointed out that scientific claims deserve attention only if they have been through the mill of scrutiny by qualified peers and by publication. The signatories stressed the need to "distinguish good science from bad science."

Dr Lachmann said: "The data that claim to show damage to the immune response cannot be taken seriously. The test is inappropriate; the results are too variable and the statistical analysis is faulty. There is nothing to support the contention that the genetic modification of food makes it dangerous to eat."

General points

1. The public debate was not helped by generic statements on the safety of GM food made by some media commentators. There is understandable unease about the use of, say, antibiotic marker genes. But that does not mean that every GM food should be banned.

2. Equally, Government reassurances on Friday 12 (notably Mr Cunningham) were bland and unfocused. The Government should have targeted the inadequacies of Dr Pusztai's research early on in the affair.

3. The debate thrives on the public muddle about what it means to be natural. During the furore it seemed that some people had the idea that DNA is a man-made chemical introduced by scientists into food. Foreign gene transfer also takes place naturally for instance when a virus replicates in the nose during a cold. And humans have been modifying genes for 5,000 years. A dog is a genetically modified wolf. A cow is a genetically modified aurochs (an extinct member of the cattle tribe).

Prof Conrad Lichtenstein of Queen Mary and Westfield College, London, conducted an experiment in which he began to introduce genes that resist virus infection into tobacco plants and was surprised to find that hundreds of similar, foreign, genes already existed within the plants' genetic make-up. It is salutary to discover that this natural genetic engineering may have helped these plants to survive.

However, our research did identify genuine concern about the environmental effects of GM crops, which could damage the countryside in several ways, from diversity of birds, insects and other wildlife, to social make-up.

4. The demand that GM experts be truly independent of industry is hard to square with more than a decade spent by Government encouraging scientists to win funding from industry. The same goes for institutes that are desperate to boost their funding with grants from industry. When it emerged that the Rowett Research Institute received grants from Monsanto, it was a gift to conspiracy theorists.

5. After BSE, we are right to be suspicious of new technology as applied to food. However, the media should be as aware of the agenda of the environmental lobby as that of the biotechnology industry. The environmental lobby has an interest in jumping aboard any lucrative fund-raising bandwagons.

6. Media have aired this issue for a very long time. For example, on 10 July 1989, Roger Highfield discussed the "Dawn of the age of Bio-Angst."

7. The media could be seen as having a vested bias towards alarmism because scaring readers and viewers is profitable. A "concerned" tabloid would probably gain interested readers by attacking what the public perceives as "unnatural" products.

The Telegraph revealed this disquiet as long ago as 6 November 1989. A Gallup poll which it commissioned to investigate public attitudes to GMOs showed:

(i) more than half of those polled did not like the idea of interfering with nature at all;

(ii) Women, the people most likely to decide about buying such new products, were far more opposed than men, with three-quarters saying that they disapproved or had doubts about food safety;

(iii) Slightly more than half of those in the survey said they would not eat a tomato which scientists have artificially altered to be fresher and tastier;

(iv) As for biotech companies releasing genetically engineered creatures into the world at large, only a quarter of the public were happy with the idea and only if there are strict legal controls.

8. The biotechnology industry should have done more to anticipate the public reaction, notably to the sale of unlabelled GM foods, by the use of focus groups and opinion polls.

9. The media have great difficulty in providing a "balanced" view of a complex scientific issue. Often, one extremist is pitched against another in the opinion columns. This has its role in the debate but a genuine attempt should be made to highlight the consensus scientific view.

I hope that this is of some help.

12 May 1999

APPENDIX 53

Supplementary memorandum submitted by the Ministry of Agriculture, Fisheries and Food, in response to a request from the Committee Clerk

1. European and national legislation regulates the certification and sale of agricultural and vegetable seeds to ensure that minimum standards are achieved before the seeds are received by farmers and growers. Since 1975, MAFF has operated a non-statutory provisional certification scheme to allow seeds of a variety to be multiplied under a controlled system in advance of acceptance on a National List and prior to entry into the statutory seed certification scheme. The seeds can be marketed only when the variety has been entered on to the National List or the EC Common Catalogue.

2. Friends of the Earth (FoE) claims in its challenge that "the Government have behaved outrageously by helping the biotech industry speed up GM food growing, behind Parliament's back and with no public support. MAFF has created a scheme with no legal base to shave two years off the time it will take to grow GM food in Britain" (FoE Press Release, 31 March 1999). However, the provisional certification scheme has been in existence since 1975 and applies to all seed whether or not it is GM. (There are in fact no genetically modified (GM) seed varieties currently in the provisional seed certification scheme, nor was the only application that has been made (in 1996) proceeded with by the applicant).

3. The changes to the provisional seed certification procedures were not made for the purposes claimed by FoE. In fact the procedures were revised to require all applicants to make a signed declaration as to whether or not their applications concerned GM seed. This was not in any way an extension of the provisional certification scheme to GM varieties. The objective was to ensure that a valid release consent under the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (as amended) was submitted with the application for provisional certification so that MAFF could check that the consent holder had ensured compliance with the release consent conditions. This revision was notified to registered seed merchants, processors and packers in England and Wales by official letter on 5 February 1999, and copied to 41 organisations identified as having an interest, including FoE.

4. The legality of the provisional seed certification scheme was challenged by FoE which lodged an application for judicial review. Subsequently, this application was stayed on 12 April 1999. MAFF has indicated that it intends to come forward shortly with specific proposals for secondary legislation to deal with the legal points raised by FoE.

Ministry of Agriculture, Fisheries and Food

May 1999

APPENDIX 54

Letter to the Chairman of the Committee from Dr Kenneth Baker, Director, Government Affairs, in response to a further question from the Committee

SCIENTIFIC ADVISORY COMMITTEE: GENETICALLY MODIFIED FOODS

In a letter dated 5 May 1999, on behalf of the Committee, the Chairman of the Committee, Dr Michael Clark MP, put forward a further question in addition to those which had been answered in oral evidence provided on 10 March 1999, and the supplementary responses provided on 27 April 1999.

Question: "The Committee is also interested to learn of whether Monsanto had undertaken any lobbying of the US Government on the wider issue of regulating GM crops and food".

Answer:

The regulations in the United States governing genetically modified crops and foods have been in place since the mid-eighties and follow a quite different structure to the way in which similar products are regulated in Europe.

As a first step, the Government provides the instructions and funds to the independent Agencies concerned to set up appropriate detailed regulations and how they would be administered. Monsanto, as did many other companies and organisations, did encourage the Government to direct the agencies to set up regulations to regulate GM crops and food.

Once the agencies had received this direction from the Government, the individual agencies (FDA, USDA, EPA) set about constructing the regulation. The agencies must follow a formal consultation process in defining regulations. The process is transparent with the agencies publishing their proposals in the US Federal Register for public comment. Monsanto, working with many other organisations and companies, did provide views and information on the structure of those regulations in the consultation process. Broadly speaking, Monsanto focused on requesting that the regulatory structures be based on a thorough and sound scientific evaluation with an accompanying clear jurisdiction and path by which the regulation would be administered. The consultation process is similar to that operating in the UK.

In implementing the regulations, the US Agencies are independent, are by law free from government interference, and the government has no role in deciding the approval or otherwise of any product—that is the role of the agency following its own science-based evaluation procedures. These procedures are also by law free from company interference although following submission of a regulatory petition by a company or other body, the Agency concerned may request further information from the submitter. Monsanto has complied with and not violated those procedures.

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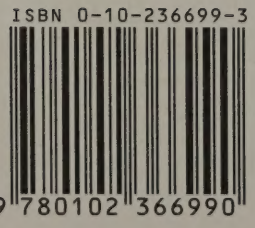

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